

STATE OF INDIANA
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
PUBLIC NOTICE NO. 20220516 – IN0002852 – D
DATE OF NOTICE: MAY 16, 2022
DATE RESPONSE DUE: JUNE 16, 2022

The Office of Water Quality proposes the following NPDES DRAFT PERMIT:

MAJOR - RENEWAL

ELANCO US, INC. - CLINTON LABORATORIES, Permit No. IN0002852, VERMILLION COUNTY, 10500 South State Rd., Clinton, IN. This is an animal health product manufacturing facility which discharges 2.2 million gallons daily of sanitary, storm water, process & non-process wastewater to the Wabash River. Permit Manager: Nicole Gardner, 317/232-8707, ngardner@idem.in.gov. Posted online at <https://www.in.gov/idem/public-notices/>.

PROCEDURES TO FILE A RESPONSE

Draft can be viewed or copied (10¢ per page) at IDEM/OWQ NPDES PS, 100 North Senate Avenue, (Rm 1203) Indianapolis, IN, 46204 (east end elevators) from 9 – 4, Mon - Fri, (except state holidays). A copy of the Draft Permit is on file at the local County Health Department. Please tell others you think would be interested in this matter. For your rights & responsibilities see: Public Notices: <https://www.in.gov/idem/public-notices/>; Citizen Guide: <https://www.in.gov/idem/resources/citizens-guide-to-idem/>. Please tell others whom you think would be interested in this matter.

Response Comments: The proposed decision to issue a permit is tentative. Interested persons are invited to submit written comments on the Draft permit. All comments must be postmarked no later than the Response Date noted to be considered in the decision to issue a Final permit. Deliver or mail all requests or comments to the attention of the Permit Writer at the above address, (mail code 65-42 PS).

To Request a Public Hearing:

Any person may request a Public Hearing. A written request must be submitted to the above address on or before the Response Date noted. The written request shall include: the name and address of the person making the request, the interest of the person making the request, persons represented by the person making the request, the reason for the request and the issues proposed for consideration at the Hearing. IDEM will determine whether to hold a Public Hearing based on the comments and the rationale for the request. Public Notice of such a Hearing will be published in at least one newspaper in the geographical area of the discharge and sent to anyone submitting written comments and/or making such request and whose name is on the mailing list at least 30 days prior to the Hearing.



INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

We Protect Hoosiers and Our Environment.

100 N. Senate Avenue • Indianapolis, IN 46204
(800) 451-6027 • (317) 232-8603 • www.idem.IN.gov

Eric J. Holcomb
Governor

Brian C. Rockensuess
Commissioner

May 16, 2022

VIA ELECTRONIC MAIL

Mr. Jason Morgan, Elanco HSE Director
Elanco US, Inc.
10500 South State Road 63
Clinton, IN 47842-7696

Dear Mr. Morgan:

Re: NPDES Permit No. IN0002852
Draft Permit
Elanco US, Inc. - Clinton Laboratories
Clinton, IN – Vermillion County

Your application and supporting documents have been reviewed and processed in accordance with rules adopted under 327 IAC 5. Enclosed is a copy of the draft NPDES Permit. Pursuant to IC 13-15-5-1, IDEM will publish the draft permit document online at <https://www.in.gov/idem/public-notice/>. Additional information on public participation can be found in the "Citizens' Guide to IDEM", available at <https://www.in.gov/idem/resources/citizens-guide-to-idem/>.

Please review this draft permit and associated documents carefully to become familiar with the proposed terms and conditions. Comments concerning the draft permit should be submitted in accordance with the procedure outlined in the enclosed public notice form. We suggest that you meet with us to discuss major concerns or objections you may have with the draft permit. Questions concerning this draft permit may be addressed to Nikki Gardner at 317/232-8707 or ngardner@idem.in.gov.

Sincerely,

Richard Hamblin, Chief
Industrial NPDES Permits Section
Office of Water Quality

Enclosures

cc: Vermillion County Health Department
Steve Bendickson, Elanco US, Inc.
Chief, Permits Section, U.S. EPA, Region 5
Jason Palin, IDEM



A State that Works

STATE OF INDIANA
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
AUTHORIZATION TO DISCHARGE UNDER THE
NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

In compliance with the provisions of the Federal Water Pollution Control Act, as amended, (33 U.S.C. 1251 et seq., the "Clean Water Act" or "CWA"), and IDEM's authority under IC 13-15,

ELANCO US, INC.
CLINTON LABORATORIES

is authorized to discharge from a pharmaceutical manufacturing facility that is located at 10500 South State Road 63 in Clinton, Indiana, to receiving waters identified as the Wabash River in accordance with effluent limitations, monitoring requirements, and other conditions set forth in Parts I and II hereof. This permit may be revoked for the nonpayment of applicable fees in accordance with IC 13-18-20.

Effective Date: _____

Expiration Date: _____

In order to receive authorization to discharge beyond the date of expiration, the permittee shall submit such information and forms as are required by the Indiana Department of Environmental Management no later than 180 days prior to the date of expiration.

Issued on _____ for the Indiana Department of Environmental Management.

Jerry Dittmer, Chief
Permits Branch
Office of Water Quality

PART I

A. EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

- The permittee is authorized to discharge from the outfall listed below in accordance with the terms and conditions of this permit. The permittee is authorized to discharge from Outfall 001, located at Latitude 39° 44' 22", Longitude -87° 23' 23". The discharge is limited to noncontact cooling water, cooling tower blowdown, boiler blowdown, treated pharmaceutical process wastewater (internal Outfall 101), treated sanitary wastewater (internal Outfall 101), RO reject water and stormwater. Samples taken in compliance with the monitoring requirements below shall be taken at a point representative of the discharge but prior to entry into the Wabash River. Such discharge shall be limited and monitored by the permittee as specified below:

DISCHARGE LIMITATIONS [1][2][6]

Outfall 001

TABLE 1

Parameter	Quantity or Loading			Quality or Concentration			Monitoring Requirements	
	Monthly Average	Daily Maximum	Units	Monthly Average	Daily Maximum	Units	Measurement Frequency	Sample Type
Flow	Report	Report	MGD	----	----	----	1 X Daily	24-Hr. Total
Temperature	----	----	----	----	Report	°F	1 X Weekly	Grab
Oil and Grease	----	----	----	Report	Report	mg/l	1 X Weekly	Grab
TRC[5]	----	----	----	0.28	0.55	mg/l	1 X Weekly	Grab
BOD ₅	Report	Report	lbs/day	----	----	----	1 X Weekly	24-Hr. Comp.
TSS	Report	Report	lbs/day	----	----	----	1 X Weekly	24-Hr. Comp.
COD	Report	Report	lbs/day	----	----	----	1 X Weekly	24-Hr. Comp.
Ammonia (as N)	Report	Report	lbs/day	----	----	----	1 X Weekly	24-Hr. Comp.
Phosphorus	----	----	----	1.0	Report	mg/l	2 X Monthly	24-Hr. Comp.
Total Mercury[4][5]	----	----	----	Report	Report	ng/l	1 X Annually	Grab
Biomonitoring	See Part I.E. of the permit							

TABLE 2

Parameter	Quality or Concentration			Monitoring Requirements	
	Daily Minimum	Daily Maximum	Units	Measurement Frequency	Sample Type
pH [3]	6.0	9.0	s.u.	1 X Daily	Grab

- [1] See Part I.B. of the permit for the minimum narrative limitations.
- [2] In the event that a new water treatment additive is to be used that will contribute to this Outfall, or changes are to be made in the use of water treatment additives, including dosage, the permittee must apply for and receive approval from IDEM prior to such discharge. Discharges of any such additives must meet Indiana water quality standards. The permittee must apply for permission to use water treatment additives by completing and submitting State Form 50000 (Application for Approval to Use Water Treatment Additives) currently available at: <https://www.in.gov/idem/forms/idem-agency-forms/>.
- [3] If the permittee collects more than one grab sample on a given day for pH, the values shall not be averaged for reporting daily maximums or daily minimums. The permittee must report the individual minimum and the individual maximum pH value of any sample during the month on the Monthly Monitoring Report form.
- [4] The permittee shall measure and report the identified metal as total recoverable metal.
- [5] The following EPA approved test methods and associated LODs and LOQs are to be used in the analysis of the effluent samples. Alternative methods may be used if first approved by IDEM and EPA, if applicable.

<u>Parameter</u>	<u>Test Method</u>	<u>LOD</u>	<u>LOQ</u>
Mercury	1631E	0.2 ng/l	0.5 ng/l
Chlorine, Total residual	4500-Cl D-2000, E-2000 or G-2000	0.02 mg/l	0.06 mg/l

Case-Specific LOD/LOQ

The permittee may determine and use a case-specific LOD or LOQ using the analytical method specified above, or any other analytical method which is approved by the Commissioner, and EPA if applicable, prior to use. The LOD shall be derived by the procedure specified for method detection limits contained in 40 CFR Part 136, Appendix B, and the LOQ shall be set equal to 3.18 times the LOD. Other methods may be used if first approved by the Commissioner.

- [6] The Stormwater Pollution Prevention Plan (SWPPP) requirements can be found in Part I.D. of this permit.

2. The permittee is authorized to discharge from the outfall listed below in accordance with the terms and conditions of this permit. The permittee is authorized to discharge from Outfall 101[1], located at Latitude 39° 44' 0.91", Longitude -87° 23' 34.48". The discharge is limited to treated pharmaceutical process wastewater and treated sanitary wastewater. Samples taken in compliance with the monitoring requirements below shall be taken at a point representative of the discharge but prior to commingling with other wastestreams. Such discharge shall be limited and monitored by the permittee as specified below:

DISCHARGE LIMITATIONS[3][9]

Outfall 101

TABLE 1

Parameter	Quantity or Loading			Quality or Concentration			Monitoring Requirements	
	Monthly Average	Daily Maximum	Units	Monthly Average	Daily Maximum	Units	Measurement Frequency	Sample Type
Flow	Report	Report	MGD	----	----	----	1 Daily	24-Hr. Total
E.coli[4]	----	----	----	125[5]	235[6]	Count/100ml	1 X Weekly	Grab
Ammonia (as N)	49	140	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
BOD ₅ Influent	Report	Report	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
BOD ₅ Effluent	66	159	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
COD Influent	Report	Report	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
COD Effluent	273	535	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
TSS	113	321	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
Acetone	0.3	0.8	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
Amyl alcohol	6.8	16.7	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
Chloroform	0.02	0.03	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
Ethanol	6.8	16.7	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
Isopropanol	2.7	6.5	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
Methanol	6.8	15.7	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
Methylene chloride	0.5	1.5	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
Phenol	0.03	0.08	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
Toluene	0.03	0.10	lbs/day	Report	Report	mg/l	2 X Monthly	Composite[2]
Acetonitrile[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
n-Amyl acetate[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
Benzene[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
n-Butyl acetate[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
Chlorobenzene[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
o-Dichlorobenzene[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]

TABLE 1 - continued

Parameter	Quantity or Loading			Quality or Concentration			Monitoring Requirements	
	Monthly Average	Daily Maximum	Units	Monthly Average	Daily Maximum	Units	Measurement Frequency	Sample Type
1,2-Dichloroethane[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
Diethyl amine[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
Dimethyl sulfoxide[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
Ethyl acetate[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
n-Heptane[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
n-Hexane[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
Isobutyraldehyde[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
Isopropyl acetate[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
Isopropyl ether[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
Methyl Cellosolve[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
Methyl formate[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
4-Methyl- 2-pentanone[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
Tetrahydrofuran[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
Triethyl amine[7]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]
Xylenes[7][8]	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite[2]

- [1] This internal outfall is located at the effluent from the membrane bioreactor, following the UV light system, prior to commingling with other wastestreams.
- [2] A “composite” sample type means a minimum of four (4) grab samples must be collected at equally spaced time intervals for the duration of the discharge within a twenty-four (24) hour period. The grab samples may be analyzed individually, and the arithmetic mean of the concentrations reported as the value for the twenty-four (24) hour period. Or, a twenty-four (24) hour composite sample may be prepared by combining the individual grab samples in the laboratory before analysis.
- [3] In the event that a new water treatment additive is to be used that will contribute to this Outfall, or changes are to be made in the use of water treatment additives, including dosage, the permittee must apply for and receive approval from IDEM prior to such discharge. Discharges of any such additives must meet Indiana water quality standards. The permittee must apply for permission to use water treatment additives by completing and submitting State Form 50000 (Application for Approval to Use Water Treatment Additives) currently available at: <https://www.in.gov/idem/forms/idem-agency-forms/>.

- [4] The effluent shall be disinfected on a continuous basis such that violations of the applicable bacteriological limitations do not occur from April 1 through October 31 annually.
- [5] The monthly average *E. coli* value shall be calculated as a geometric mean. Per 327 IAC 5-10-6, the concentration of *E. coli* shall not exceed one hundred twenty-five (125) cfu or mpn per 100 milliliters as a geometric mean of the effluent samples taken in a calendar month. No samples may be excluded when calculating the monthly geometric mean.
- [6] If less than ten samples are taken and analyzed for *E. coli* in a calendar month, no samples may exceed two hundred thirty-five (235) cfu or mpn as a daily maximum. However, when ten (10) or more samples are taken and analyzed for *E. coli* in a calendar month, not more than ten percent (10%) of those samples may exceed two hundred thirty-five (235) cfu or mpn as a daily maximum. When calculating ten percent, the result must not be rounded up. In reporting for compliance purposes on the Discharge Monitoring Report (DMR) form, the permittee shall record the highest non-excluded value for the daily maximum.
- [7] For the annotated parameters, within thirty (30) days of becoming aware of the fact, the permittee must notify IDEM if it plans to use or generate or does use or generate the parameter.
- [8] Xylenes means a combination of the three isomers: o-xylene, m-xylene, and p-xylene.
- [9] The permittee must complete and submit Item V of NPDES application Form 2C (State Form 55637) with the next permit renewal application.

B. MINIMUM NARRATIVE LIMITATIONS

At all times the discharge from any and all point sources specified within this permit shall not cause receiving waters:

1. including waters within the mixing zone, to contain substances, materials, floating debris, oil, scum attributable to municipal, industrial, agricultural, and other land use practices, or other discharges that do any of the following:
 - a. will settle to form putrescent or otherwise objectionable deposits;
 - b. are in amounts sufficient to be unsightly or deleterious;
 - c. produce color, visible oil sheen, odor, or other conditions in such degree as to create a nuisance;
 - d. are in amounts sufficient to be acutely toxic to , or to otherwise severely injure or kill aquatic life, other animals, plants, or humans;
 - e. are in concentrations or combinations that will cause or contribute to the growth of aquatic plants or algae to such a degree as to create a nuisance, be unsightly, or otherwise impair the designated uses.
2. outside the mixing zone, to contain substances in concentrations that on the basis of available scientific data are believed to be sufficient to injure, be chronically toxic to, or be carcinogenic, mutagenic, or teratogenic to humans, animals, aquatic life, or plants.

C. MONITORING AND REPORTING

1. Representative Sampling

Samples and measurements taken as required herein shall be representative of the volume and nature of the monitored discharge flow and shall be taken at times which reflect the full range and concentration of effluent parameters normally expected to be present. Samples shall not be taken at times to avoid showing elevated levels of any parameters.

2. Monthly Reporting

The permittee shall submit monitoring reports to the Indiana Department of Environmental Management (IDEM) containing results obtained during the previous month and shall be submitted no later than the 28th day of the month following each completed monitoring period. The first report shall be submitted by the 28th day of the month following the month in which the permit becomes effective.

These reports shall include, but not necessarily be limited to, the Discharge Monitoring Report (DMR) and the Monthly Monitoring Report (MMR). All reports shall be submitted electronically by using the NetDMR application, upon registration, receipt of the NetDMR Subscriber Agreement, and IDEM approval of the proposed NetDMR Signatory. Access the NetDMR website (for initial registration and DMR/MMR submittal) via CDX at: <https://cdx.epa.gov/>. The Regional Administrator may request the permittee to submit monitoring reports to the Environmental Protection Agency if it is deemed necessary to assure compliance with the permit. See Part II.C.10 of this permit for Future Electronic Reporting Requirements.

- a. Calculations that require averaging of measurements of daily values (both concentrations and mass) shall use an arithmetic mean, except the monthly average for *E. coli* shall be calculated as a geometric mean.
- b. Daily effluent values (both mass and concentration) that are less than the LOQ that are used to determine the monthly average effluent level shall be accommodated in calculation of the average using statistical methods that have been approved by the Commissioner.
- c. Effluent concentrations less than the LOD shall be reported on the Discharge Monitoring Report (DMR) forms as < (less than) the value of the LOD. For example, if a substance is not detected at a concentration of 0.1 µg/l, report the value as <0.1 µg/l.
- d. Effluent concentrations greater than or equal to the LOD and less than the LOQ that are reported on a DMR shall be reported as the actual value and annotated on the DMR to indicate that the value is not quantifiable.
- e. Mass discharge values which are calculated from concentrations reported as less than the value of the limit of detection shall be reported as less than the corresponding mass discharge value.
- f. Mass discharge values that are calculated from effluent concentrations greater than the limit of detection shall be reported as the calculated value.

3. Definitions

- a. "Monthly Average" means the total mass or flow-weighted concentration of all daily discharges during a calendar month on which daily discharges are sampled or measured, divided by the number of daily discharges sampled and/or measured during such calendar month.

The monthly average discharge limitation is the highest allowable average monthly discharge for any calendar month.

- b. “Daily Discharge” means the total mass of a pollutant discharged during the calendar day or, in the case of a pollutant limited in terms other than mass pursuant to 327 IAC 5-2-11(e), the average concentration or other measurement of the pollutant specified over the calendar day or any twenty-four hour period that reasonably represents the calendar day for the purposes of sampling.
- c. “Daily Maximum” means the maximum allowable daily discharge for any calendar day.
- d. A “24-hour composite sample” means a sample consisting of at least 3 individual flow-proportioned samples of wastewater, taken by the grab sample method or by an automatic sampler, which are taken at approximately equally spaced time intervals for the duration of the discharge within a 24-hour period and which are combined prior to analysis. A flow-proportioned composite sample may be obtained by:
 - (1) recording the discharge flow rate at the time each individual sample is taken,
 - (2) adding together the discharge flow rates recorded from each individuals sampling time to formulate the “total flow” value,
 - (3) the discharge flow rate of each individual sampling time is divided by the total flow value to determine its percentage of the total flow value,
 - (4) then multiply the volume of the total composite sample by each individual sample’s percentage to determine the volume of that individual sample which will be included in the total composite sample.
- e. “Concentration” means the weight of any given material present in a unit volume of liquid. Unless otherwise indicated in this permit, concentration values shall be expressed in milligrams per liter (mg/l).
- f. The “Regional Administrator” is defined as the Region 5 Administrator, U.S. EPA, located at 77 West Jackson Boulevard, Chicago, Illinois 60604.

- g. The "Commissioner" is defined as the Commissioner of the Indiana Department of Environmental Management, which is located at the following address: 100 North Senate Avenue, Indianapolis, Indiana 46204.
- h. "Limit of Detection" or "LOD" means the minimum concentration of a substance that can be measured and reported with ninety-nine percent (99%) confidence that the analyte concentration is greater than zero (0) for a particular analytical method and sample matrix.
- i. "Limit of Quantitation" or "LOQ" means a measurement of the concentration of a contaminant obtained by using a specified laboratory procedure calibrated at a specified concentration above the method detection level. It is considered the lowest concentration at which a particular contaminant can be quantitatively measured using a specified laboratory procedure for monitoring of the contaminant. This term is also sometimes called limit of quantification or quantification level.
- j. "Method Detection Level" or "MDL" means the minimum concentration of an analyte (substance) that can be measured and reported with a ninety-nine percent (99%) confidence that the analyte concentration is greater than zero (0) as determined by procedure set forth in 40 CFR 136, Appendix B. The method detection level or MDL is equivalent to the LOD.
- k. "Grab Sample" means a sample which is taken from a wastestream on a one-time basis without consideration of the flow rate of the wastestream and without considerations of time.

4. Test Procedures

The analytical and sampling methods used shall conform to the version of 40 CFR 136 incorporated by reference in 327 IAC 5. Different but equivalent methods are allowable if they receive the prior written approval of the Commissioner and the U.S. Environmental Protection Agency. When more than one test procedure is approved for the purposes of the NPDES program under 40 CFR 136 for the analysis of a pollutant or pollutant parameter, the test procedure must be sufficiently sensitive as defined at 40 CFR 122.21(e)(3) and 122.44(i)(1)(iv).

5. Recording of Results

For each measurement or sample taken pursuant to the requirements of this permit, the permittee shall maintain records of all monitoring information and monitoring activities, including:

- a. The date, exact place and time of sampling or measurement;
- b. The person(s) who performed the sampling or measurements;
- c. The date(s) analyses were performed;
- d. The person(s) who performed the analyses;
- e. The analytical techniques or methods used; and
- f. The results of such measurements and analyses.

6. Additional Monitoring by Permittee

If the permittee monitors any pollutant at the location(s) designated herein more frequently than required by this permit, using approved analytical methods as specified above, the results of this monitoring shall be included in the calculation and reporting of the values required in the monthly Discharge Monitoring Report (DMR) and Monthly Monitoring Report (MMR). Such increased frequency shall also be indicated. Other monitoring data not specifically required in this permit (such as internal process or internal waste stream data) which is collected by or for the permittee need not be submitted unless requested by the Commissioner.

7. Records Retention

All records and information resulting from the monitoring activities required by this permit, including all records of analyses performed and calibration and maintenance of instrumentation and recording from continuous monitoring instrumentation, shall be retained for a minimum of three (3) years. In cases where the original records are kept at another location, a copy of all such records shall be kept at the permitted facility. The three years shall be extended:

- a. automatically during the course of any unresolved litigation regarding the discharge of pollutants by the permittee or regarding promulgated effluent guidelines applicable to the permittee; or
- b. as requested by the Regional Administrator or the Indiana Department of Environmental Management.

D. STORMWATER POLLUTION PREVENTION PLAN (SWPPP)

1. Development of Stormwater Pollution Prevention Plan

Within 12 months from the effective date of this permit, the permittee is required to revise and update the current SWPPP for the permitted facility. The plan shall at a minimum include the following:

- a. Identify potential sources of pollution that may reasonably be expected to affect the quality of stormwater discharges associated with industrial activity from the facility. Stormwater associated with industrial activity is defined at 40 CFR 122.26(b)(14) and includes, but is not limited to, the discharge from any conveyance that is used for collecting and conveying stormwater and that is directly related to manufacturing, processing or raw materials storage areas at an industrial plant;
- b. Describe practices and measures to be used in reducing the potential for pollutants to be exposed to stormwater; and
- c. Assure compliance with the terms and conditions of this permit.

2. Contents of Stormwater Pollution Prevention Plan

The plan shall include, at a minimum, the following items:

- a. Stormwater Pollution Prevention Team -The plan shall list, by position title, the member or members of the permittee's stormwater pollution prevention team who are responsible for developing the stormwater pollution prevention plan (SWPPP) and assisting the facility or plant manager in its implementation, maintenance, and revision. The plan shall clearly identify the responsibilities of each stormwater pollution prevention team member.
- b. Description of Potential Pollutant Sources – The plan shall provide a map and description of all areas at the facility that generate stormwater discharges associated with industrial activity and have a reasonable potential for stormwater to be exposed to pollutants. The plan shall identify all activities and significant materials (defined in 40 CFR 122.26(b)(12)), which may potentially be significant pollutant sources. As a minimum, the plan shall contain the following:
 - (1) A soils map indicating the types of soils found on the facility property and showing the boundaries of the facility property outlined in a contrasting color. If a facility's property only has impervious surfaces, the soils map requirement can be omitted.

- (2) A graphical representation, such as an aerial photograph or site layout maps, drawn to an appropriate scale, which contains a legend and compass coordinates, indicating, at a minimum, the following:
 - (A) All on-site stormwater drainage and discharge conveyances, which may include pipes, ditches, swales, and erosion channels, related to a stormwater discharge.
 - (B) Known adjacent property drainage and discharge conveyances, if directly associated with run-off from the facility.
 - (C) All on-site and known adjacent property water bodies, including wetlands and springs.
 - (D) An outline of the drainage area for each outfall discharging stormwater.
 - (E) An outline of the facility property, indicating directional flows, via arrows, of surface drainage patterns.
 - (F) An outline of impervious surfaces, which includes pavement and buildings, and an estimate of the impervious and pervious surface square footage for each drainage area placed in a map legend.
 - (G) On-site injection wells, as applicable.
 - (H) On-site wells used as potable water sources, as applicable.
 - (I) All existing major structural control measures to reduce pollutants in stormwater run-off.
 - (J) All existing and historical underground or aboveground storage tank locations, as applicable.
 - (K) All permanently designated plowed or dumped snow storage locations.
 - (L) All loading and unloading areas for solid and liquid bulk materials.

- (M) All existing and historical outdoor storage areas for raw materials, intermediary products, final products, and waste materials.
- (N) All existing or historical outdoor storage areas for fuels, processing equipment, and other containerized materials, for example, in drums and totes.
- (O) Outdoor processing areas.
- (P) Dust or particulate generating process areas.
- (Q) Outdoor assigned waste storage or disposal areas.
- (R) Pesticide or herbicide application areas.
- (S) Vehicular access roads.

The on-site mapping of items listed in clauses (J) through (S) is required only in those areas that generate stormwater discharges exposed to industrial activity and have a reasonable potential for stormwater exposure to pollutants. The mapping of historical locations is only required if the historical locations have a reasonable potential for stormwater exposure to historical pollutants.

- (3) An area site map that indicates:
 - (A) The topographic relief or similar elevations to determine surface drainage patterns;
 - (B) The facility boundaries outlined in contrasting color;
 - (C) All receiving waters; and
 - (D) All known drinking water wells; and

Includes at a minimum, the features in clauses (A), (C), and (D) within a one-fourth (1/4) mile radius beyond the property boundaries of the facility. This map must be to scale and include a legend and compass coordinates.

- (4) A narrative description of areas that generate stormwater discharges associated with industrial activity and have a reasonable potential for stormwater exposure to pollutants, including descriptions for any existing or historical areas listed in Part I.D.2.b.(2)(J) through (S) of this permit, and any other areas thought to generate stormwater discharges associated with industrial activity and be a reasonable potential source of stormwater exposure to pollutants. The narrative descriptions for each identified area must include the following:
- (A) Type and typical quantity of materials present in the area.
 - (B) Methods of storage, including presence of any secondary containment measures.
 - (C) Any remedial actions undertaken in the area to eliminate pollutant sources or exposure of stormwater to those sources. If a corrective action plan was developed, the type of remedial action and plan date shall be referenced.
 - (D) Any significant release or spill history dating back a period of three (3) years from the effective date of this permit, in the identified area, for materials spilled outside of secondary containment structures and impervious surfaces in excess of their reportable quantity, including the following:
 - i. The date and type of material released or spilled.
 - ii. The estimated volume released or spilled.
 - iii. A description of the remedial actions undertaken, including disposal or treatment.

Depending on the adequacy or completeness of the remedial actions, the spill history shall be used to determine additional pollutant sources that may be exposed to stormwater. In subsequent permit terms, the history shall date back for a period of five (5) years from the date of the permit renewal application.

- (E) Where the chemicals or materials have the potential to be exposed to stormwater discharges, the descriptions for each identified area must include a risk identification analysis of chemicals or materials stored or used within the area. The analysis must include the following:
 - i. Toxicity data of chemicals or materials used within the area, referencing appropriate material safety data sheet information locations.
 - ii. The frequency and typical quantity of listed chemicals or materials to be stored within the area.
 - iii. Potential ways in which stormwater discharges may be exposed to listed chemicals and materials.
 - iv. The likelihood of the listed chemicals and materials to come into contact with stormwater.
- (5) A narrative description of existing and planned management practices and measures to improve the quality of stormwater run-off entering a water of the state. Descriptions must be created for existing or historical areas listed in Part I.D.2.b.(2)(J) through (S) of this permit and any other areas thought to generate stormwater discharges associated with industrial activity and be a potential source of stormwater exposure to pollutants. The description must include the following:
 - (A) Any existing or planned structural and nonstructural control practices and measures.
 - (B) Any treatment the stormwater receives prior to leaving the facility property or entering a water of the state.
 - (C) The ultimate disposal of any solid or fluid wastes collected in structural control measures other than by discharge.
- (6) If applicable, the specific control practices and measures for potential pollutant source areas must include the following

- (A) Identification of areas that due to topography, activities, or other factors have a high potential for significant soil erosion and identify and implement measures to limit erosion.
 - (B) A plan to cover, or otherwise reduce the potential for pollutants in stormwater discharge from deicing salt and sand or other commercial or industrial material storage piles, except for exposure resulting from the addition or removal of materials from the pile. For piles that do not have the potential for polluting stormwater runoff, the plan needs to provide the basis for determining no exposure potential. The plan must be included in the SWPPP.
 - (C) Storage piles of sand and salt or other commercial or industrial materials must be stored in a manner to reduce the potential for polluted stormwater runoff and in accordance with the plan required under Part I.D.2.b.(6)(B) of this permit
- (7) Information or other documentation required under Part I.D.5. of this permit.
- (8) The results of stormwater monitoring. The monitoring data must include completed field data sheets, chain-of-custody forms, and laboratory results. If the monitoring data are not placed into the facility's SWPPP, the on-site location for storage of the information must be reference in the SWPPP. As two (2) or more sample monitoring events are completed, the laboratory results must be compared to indicate water quality improvements in the run-off from the facility. If the parameters and sample type are identical, historical stormwater monitoring data at each discharge outfall, or representative discharge outfall, if applicable, can be used in the comparison to provide data that is more reflective of initial water quality conditions.
- (9) A mapped or narrative description of any such management practice or measure pursuant to subsection Part I.D.3.d. of the permit must be added to the SWPPP.

3. Planning and Implementation of Measures and Practices in the Stormwater Pollution Prevention Plan

For areas of the facility that generate stormwater discharges and have a reasonable potential for stormwater exposure to pollutants, stormwater exposure to pollutants must be minimized. To ensure this reduction, the following practices and measures must be planned and implemented:

- a. A written preventative maintenance program, including the following:
 - (1) Implementation of good housekeeping practices to ensure the facility will be operated in a clean and orderly manner and that pollutants will not have the potential to be exposed to stormwater via vehicular tracking or other means.
 - (2) Maintenance of stormwater management measures, for example, catch basins or the cleaning of oil or water separators. All maintenance must be documented and either contained in, or have the on-site record keeping location referenced in, the SWPPP.
 - (3) Inspection and testing of facility equipment and systems that are in areas of the facility that generate stormwater discharges and have a reasonable potential for stormwater exposure to pollutants to ensure appropriate maintenance of such equipment and systems and to uncover conditions that could cause breakdowns or failures resulting in discharges of pollutants to surface waters.
 - (4) At a minimum, quarterly inspections of the stormwater management measures and stormwater run-off conveyances. Inspections must be documented and either contained in, or have the on-site record keeping location referenced in, the SWPPP.
 - (5) An employee training program to inform personnel at all levels of responsibility that have the potential to engage in industrial activities that impact stormwater quality of the components and goals of the SWPPP. Training must occur at a minimum annually and should address topics such as spill response, good housekeeping, and material management practices. All employee training sessions, including relevant stormwater topics discussed and a roster of attendees, must be documented and either contained in, or have the on-site record keeping location referenced in, the SWPPP.

- b. A written spill response program, including the following:
 - (1) Location, description, and quantity of all response materials and equipment.
 - (2) Response procedures for facility personnel to respond to a release.
 - (3) Contact information for reporting spills, both for facility staff and external emergency response entities.
- c. Non-Stormwater Discharges – The permittee must document that it has evaluated for the presence of non-stormwater discharges not authorized by an NPDES permit. Any non-stormwater discharges must either be eliminated or incorporated into this permit. Documentation of non-stormwater discharges shall include a written non-stormwater assessment, including the following:
 - (1) A statement that stormwater discharges entering a water of the state have been evaluated for the presence of illicit discharges and non-stormwater contributions.
 - (2) Detergent or solvent-based washing of equipment or vehicles that would allow washwater additives to enter any stormwater drainage system or receiving water shall not be allowed at this facility unless authorized under a NPDES permit.
 - (3) All interior maintenance area floor drains with the potential for maintenance fluids or other materials to enter storm sewers must be either sealed, connected to a sanitary sewer with prior authorization, or authorized under a NPDES permit. The sealing, sanitary sewer connecting, or permitting of drains under this item must be documented in the written non-stormwater assessment program.
 - (4) The statement shall include a description of the method used, the date of any testing, and the on-site drainage points that were directly observed during the test.
- d. If parameter reductions are not indicated in a comparison conducted under Part. I.D.2.b.(8) of this permit and they cannot be attributed to laboratory error or significant variability in the rainfall events, the source of the pollutant parameter must be investigated and either eliminated or reduced via a management practice or measure to the extent technologically practicable and cost beneficial. A lack of reduction does not, in and of itself, constitute a violation of this permit.

If parameter concentrations are at, or below, laboratory detection limitations, further reductions are not necessary.

4. Annual Review and Reports

At least once every twelve (12) months, the permittee shall conduct an annual review of the stormwater control measures and practices to determine if modifications are necessary to meet the effluent limitations in this permit. The results of the annual review must be documented in a report that shall be retained within the SWPPP.

The permittee shall submit an annual report that contains the following information at a minimum:

- (a) Any changes from the original Form 2F application,
- (b) Any changes to the facility, the facility's operations or industrial activities that may reasonably be expected to affect the quality of stormwater discharges associated with industrial activity from the facility,
- (c) A copy of the comparison of all stormwater sampling data results included in the facility's SWPPP and required under this permit,
- (d) Any additional best management practices (BMPs) implemented, or corrective measures taken, as a result of sampling data results, and
- (e) Any additional BMPs implemented, or corrective measures taken, as a result of the annual review.

The report must be submitted to the Industrial NPDES Permit Section, as well as the Compliance Branch, on an annual basis. The report may be submitted by email to the Industrial NPDES Permit Section at OWQWWPER@idem.in.gov and to the Compliance Branch at wwReports@idem.in.gov. The email subject line should include the NPDES Permit # and the type of report being submitted (Annual Stormwater Report). The permittee's first annual review report will be due twelve (12) months from the effective date of the permit. All subsequent annual review reports will be due no later than the anniversary of the effective date of the permit.

5. General Requirements – The SWPPP must meet the following general requirements:

- (a) The plan shall be certified by a qualified professional. The term qualified professional means an individual who is trained and experienced in stormwater treatment techniques and related fields as

may be demonstrated by state registration, professional certification, experience, or completion of course work that enable the individual to make sound, professional judgments regarding stormwater control or treatment and monitoring, pollutant fate and transport, and drainage planning.

- (b) The plan shall be retained at the facility and be available for review by a representative of the Commissioner upon request
- (c) The plan must be revised and updated as required.
- (d) The permittee shall amend the plan when either of the following occur:
 - (1) Whenever there is a change in design, construction, operation, or maintenance at the facility, which may have a significant effect on the potential for the discharge of pollutants to surface waters of the state. Within sixty (60) days of amending the plan as a result of the conditions above, the permittee shall make the required changes to the SWPPP.
 - (2) Upon written notice by the Commissioner that the SWPPP proves to be ineffective in controlling pollutants in stormwater discharges associated with industrial activity. Within sixty (60) days of such notification from the commissioner, the permittee shall make the required changes to the SWPPP and shall submit the amended plan to the Commissioner for review.
- (e) If the permittee has other written plans, required under applicable federal or state law, such as operation and maintenance, spill prevention control and countermeasures (SPCC), or risk contingency plans, which fulfill certain requirements of an SWPPP, these plans may be referenced, at the permittee's discretion, in the appropriate sections of the SWPPP to meet those section requirements.
- (f) The permittee may combine the requirements of the SWPPP with another written plan if:
 - (1) The plan is retained at the facility and available for review;
 - (2) All the requirements of the SWPP are contained within the plan; and
 - (3) A separate, labeled section is utilized in the plan for the SWPPP requirements.

E. WHOLE EFFLUENT TOXICITY TESTING REQUIREMENTS

To adequately assess the effects of the effluent on aquatic life, the permittee is required by this section of the permit to conduct chronic whole effluent toxicity (WET) testing. Part I.E.1. of this permit describes the testing procedures and Part I.E.2. describes the toxicity reduction evaluation (TRE) which is only required if the effluent demonstrates toxicity in two (2) consecutive toxicity tests as described in Part I.E.1.f.

1. Whole Effluent Toxicity (WET) Tests

The permittee must conduct the series of aquatic toxicity tests specified in Part I.E.1.d. to monitor the acute and chronic toxicity of the effluent discharged from Outfall 001.

If toxicity is demonstrated in two (2) consecutive toxicity tests, as described in Part I.E.1.f., with any test species during the term of the permit, the permittee is required to conduct a TRE under Part I.E.2.

a. Toxicity Test Procedures and Data Analysis

- (1) All test organisms, test procedures and quality assurance criteria used must be in accordance with the Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Water to Freshwater Organisms, Fourth Edition, Section 11, Fathead Minnow (*Pimephales promelas*) Larval Survival and Growth Test Method 1000.0, and Section 13, Daphnid (*Ceriodaphnia dubia*) Survival and Reproduction Test Method 1002.0, EPA 821-R-02-013, October 2002 (hereinafter "Chronic Toxicity Test Method"), or most recent update that conforms to the version of 40 CFR 136 incorporated by reference in 327 IAC 5. [References to specific portions of the Chronic Toxicity Test Method contained in this Part I.E. are provided for informational purposes. If the Chronic Toxicity Test Method is updated, the corresponding provisions of that updated method would be applicable.]
- (2) Any circumstances not covered by the above methods, or that require deviation from the specified methods must first be approved by the IDEM Permits Branch.

- (3) The determination of acute and chronic endpoints of toxicity (LC₅₀, NOEC and IC₂₅ values) must be made in accordance with the procedures in Section 9, "Chronic Toxicity Test Endpoints and Data Analysis" and the Data Analysis procedures as outlined in Section 11 for fathead minnow (Test Method 1000.0; see flowcharts in Figures 5, 6 and 9) and Section 13 for *Ceriodaphnia dubia* (Test Method 1002.0; see flowcharts in Figures 4 and 6) of the Chronic Toxicity Test Method. The IC₂₅ value together with 95% confidence intervals calculated by the Linear Interpolation and Bootstrap Methods in Appendix M of the Chronic Toxicity Test Method must be determined in addition to the NOEC value.

b. Types of Whole Effluent Toxicity Tests

- (1) Tests may include a 3-brood (7-day) definitive static-renewal daphnid (*Ceriodaphnia dubia*) survival and reproduction toxicity test and a 7-day definitive static-renewal fathead minnow (*Pimephales promelas*) larval survival and growth toxicity test.
- (2) All tests must be conducted using 24-hour composite samples of final effluent. Three effluent samples are to be collected on alternate days (e.g., collected on days one, three and five). The first effluent sample will be used for test initiation and for test solution renewal on day 2. The second effluent sample will be used for test solution renewal on days 3 and 4. The third effluent sample will be used for test solution renewal on days 5, 6 and 7. If shipping problems are encountered with renewal samples after a test has been initiated, the most recently used sample may continue to be used for test renewal, if first approved by the IDEM Permits Branch, but for no longer than 72 hours after first use.
- (3) The whole effluent dilution series for the definitive test must include a control and at least five effluent concentrations with a minimum dilution factor of 0.5. The effluent concentrations selected must include and, if practicable, bracket the effluent concentrations associated with the determinations of acute and chronic toxicity provided in Part I.E.1.f. Guidance on selecting effluent test concentrations is included in Section 8.10 of the Chronic Toxicity Test Method. The use of an alternate procedure for selecting test concentrations must first be approved by the IDEM Permits Branch.

- (4) If, in any control, more than 10% of the test organisms die in the first 48 hours with a daphnid species or the first 96 hours with fathead minnow, or more than 20% of the test organisms die in 7 days, that test is considered invalid and the toxicity test must be repeated. In addition, if in the *Ceriodaphnia dubia* survival and reproduction test, the average number of young produced per surviving female in the control group is less than 15, or if 60% of surviving control females have less than three broods; and in the fathead minnow (*Pimephales promelas*) survival and growth test, if the mean dry weight of surviving fish in the control group is less than 0.25 mg, that test is considered invalid and must also be repeated. All other test conditions and test acceptability criteria for the fathead minnow (*Pimephales promelas*) and *Ceriodaphnia dubia* chronic toxicity tests must be in accordance with the test requirements in Section 11 (Test Method 1000.0), Table 1 and Section 13 (Test Method 1002.0), Table 3, respectively, of the Chronic Toxicity Test Method.

c. Effluent Sample Collection and Chemical Analysis

- (1) Whole effluent samples taken for the purposes of toxicity testing must be 24-hour composite samples collected at a point that is representative of the final effluent, but prior to discharge. Effluent sampling for the toxicity testing may be coordinated with other permit sampling requirements as appropriate to avoid duplication. First use of the whole effluent toxicity testing samples must not exceed 36 hours after termination of the 24-hour composite sample collection and must not be used for longer than 72 hours after first use. For discharges of less than 24 hours in duration, composite samples must be collected for the duration of the discharge within a 24-hour period (see "24-hour composite sample" definition in Part I.C.3. of this permit).
- (2) Chemical analysis must accompany each effluent sample taken for toxicity testing, including each sample taken for the repeat testing as outlined in Part I.E.1.f.(3). The chemical analysis detailed in Part I.A.1. must be conducted for the effluent sample in accordance with Part I.C.4. of this permit.

d. Toxicity Testing Species, Frequency and Duration

Chronic toxicity testing for *Ceriodaphnia dubia* and fathead minnow (*Pimephales promelas*) must be conducted once annually, as calculated from the effective date of the permit, for the duration of the permit.

If a TRE is initiated during the term of the permit, after receiving notification under Part I.E.1.e, the Compliance Data Section will suspend the toxicity testing requirements above for the term of the TRE compliance schedule described in Part I.E.2. After successful completion of the TRE, the toxicity tests established under Part I.E.2.c.(4) must be conducted once annually, as calculated from the first day of the first month following successful completion of the post-TRE toxicity tests (see Part I.E.2.c.(4)), for the remainder of the permit term.

e. Reporting

- (1) Notifications of the failure of two (2) consecutive toxicity tests and the intent to begin the implementation of a toxicity reduction evaluation (TRE) under Part I.E.1.f.(4) must be submitted in writing to the Compliance Data Section of IDEM's Office of Water Quality.
- (2) Results of all toxicity tests, including invalid tests, must be reported to IDEM according to the general format and content recommended in the Chronic Toxicity Test Method, Section 10, "Report Preparation and Test Review". However, only the results of valid toxicity tests are to be reported on the discharge monitoring report (DMR). The results of the toxicity tests and laboratory report are due by the earlier of 60 days after completion of the test or the 28th day of the month following the end of the period established in Part I.E.1.d.
- (3) The full whole effluent toxicity (WET) test laboratory report must be submitted to IDEM electronically as an attachment to an e-mail to the Compliance Data Section at wwreports@idem.IN.gov. The results must also be submitted via NetDMR.
- (4) For quality control and ongoing laboratory performance, the laboratory report must include results from appropriate standard reference toxicant tests. This will consist of acute (LC₅₀ values), if available, and chronic (NOEC, LOEC and IC₂₅ values) endpoints of toxicity obtained from reference toxicant tests conducted within 30 days of the most current effluent toxicity tests and from similarly obtained historical reference toxicant data with mean values and appropriate ranges for each species tested for at least three months to one year. Toxicity test laboratory reports must also include copies of chain-of-custody records and laboratory raw data sheets.

- (5) Statistical procedures used to analyze and interpret toxicity data (e.g., Fisher's Exact Test and Steel's Many-one Rank Test for 7-day survival of test organisms; tests of normality (e.g., Shapiro-Wilk's Test) and homogeneity of variance (e.g., Bartlett's Test); appropriate parametric (e.g., Dunnett's Test) and non-parametric (e.g., Steel's Many-one Rank Test) significance tests and point estimates (IC₂₅) of effluent toxicity, etc.; together with graphical presentation of survival, growth and reproduction of test organisms), including critical values, levels of significance and 95% confidence intervals, must be described and included as part of the toxicity test laboratory report.
- (6) For valid toxicity tests, the whole effluent toxicity (WET) test laboratory report must include a summary table of the results for each species tested as shown in the table presented below. This table will provide toxicity test results, reported in acute toxic units (TU_a) and chronic toxic units (TU_c), for evaluation under Part I.E.1.f. and reporting on the discharge monitoring report (DMR).

Test Organism [1]	Test Type	Endpoint [2]	Units	Result	Compliance Limit [6]	Pass/Fail [7]	Reporting
<i>Ceriodaphnia dubia</i>	3-brood (7-day) Definitive Static-Renewal Survival and Reproduction	48-hr. LC ₅₀	%	Report			Laboratory Report
			TU _a	Report			
		NOEC Survival	%	Report			
			TU _c	Report			
		NOEC Reproduction	%	Report			
			TU _c	Report			
		IC ₂₅ Reproduction	%	Report			
			TU _c	Report			
		Toxicity (acute) [3]	TU _a	Report [5]	8.8	Report	Laboratory Report and NetDMR (Parameter Code 61425)
		Toxicity (chronic) [4]	TU _c	Report [5]	53	Report	Laboratory Report and NetDMR (Parameter Code 61426)
<i>Pimephales promelas</i>	7-day Definitive Static-Renewal Larval Survival and Growth	96-hr. LC ₅₀	%	Report			Laboratory Report
			TU _a	Report			
		NOEC Survival	%	Report			
			TU _c	Report			
		NOEC Growth	%	Report			
			TU _c	Report			
		IC ₂₅ Growth	%	Report			
			TU _c	Report			
		Toxicity (acute) [3]	TU _a	Report [5]	8.8	Report	Laboratory Report and NetDMR (Parameter Code 61427)
		Toxicity (chronic) [4]	TU _c	Report [5]	53	Report	Laboratory Report and NetDMR (Parameter Code 61428)

[1] For the whole effluent toxicity (WET) test laboratory report, eliminate from the table any species that was not tested.

[2] A separate acute test is not required. The endpoint of acute toxicity must be extrapolated from the chronic toxicity test.

[3] The toxicity (acute) endpoint for *Ceriodaphnia dubia* is the 48-hr. LC₅₀ result reported in acute toxic units (TU_a). The toxicity (acute) endpoint for *Pimephales promelas* is the 96-hr. LC₅₀ result reported in acute toxic units (TU_a).

[4] The toxicity (chronic) endpoint for *Ceriodaphnia dubia* is the higher of the NOEC Survival, NOEC Reproduction and IC₂₅ Reproduction values reported in chronic toxic units (TU_c). The

toxicity (chronic) endpoint for *Pimephales promelas* is the higher of the NOEC Survival, NOEC Growth and IC₂₅ Growth values reported in chronic toxic units (TU_c).

[5] Report the values for acute and chronic endpoints of toxicity determined in [3] and [4] for the corresponding species. These values are the ones that need to be reported on the discharge monitoring report (DMR).

[6] These values do not represent effluent limitations, but rather exceedance of these values results in a demonstration of toxicity that triggers additional action and reporting by the permittee.

[7] If the toxicity result (in TUs) is less than or equal to the compliance limit, report "Pass". If the toxicity result (in TUs) exceeds the compliance limit, report "Fail".

f. Demonstration of Toxicity

- (1) Toxicity (acute) will be demonstrated if the effluent is observed to have exceeded 8.8 TU_a (acute toxic units) for *Ceriodaphnia dubia* in 48 hours or in 96 hours for *Pimephales promelas*. For this purpose, a separate acute toxicity test is not required. The results for the acute toxicity demonstration must be extrapolated from the chronic toxicity test. For the purpose of selecting test concentrations under Part I.E.1.b.(2), the effluent concentration associated with acute toxicity is 11.4%.
- (2) Toxicity (chronic) will be demonstrated if the effluent is observed to have exceeded 60.4 TU_c (chronic toxic units) for *Ceriodaphnia dubia* or *Pimephales promelas* from the chronic toxicity test. For the purpose of selecting test concentrations under Part I.E.1.b.(2), the effluent concentration associated with chronic toxicity is 1.9%.
- (3) If toxicity (acute) or toxicity (chronic) is demonstrated in any of the chronic toxicity tests specified above, a repeat chronic toxicity test using the procedures in Part I.E.1. of this permit and the same test species must be initiated within two (2) weeks of test failure. During the sampling for any repeat tests, the permittee must also collect and preserve sufficient effluent samples for use in any toxicity identification evaluation (TIE) and/or toxicity reduction evaluation (TRE), if necessary.
- (4) If any two (2) consecutive chronic toxicity tests, including any and all repeat tests, demonstrate acute or chronic toxicity, the permittee must notify the Compliance Data Section under Part I.E.1.e. within 30 days of the date of termination of the second test, and begin the implementation of a toxicity reduction evaluation (TRE) as described in Part I.E.2. After receiving notification from the permittee, the Compliance Data Section will suspend the whole effluent toxicity testing requirements in Part I.E.1. for the term of the TRE compliance schedule.

g. Definitions

- (1) "Acute toxic unit" or "TU_a" is defined as $100/LC_{50}$ where the LC_{50} is expressed as a percent effluent in the test medium of an acute whole effluent toxicity (WET) test that is statistically or graphically estimated to be lethal to fifty percent (50%) of the test organisms.
- (2) "Chronic toxic unit" or "TU_c" is defined as $100/NOEC$ or $100/IC_{25}$, where the $NOEC$ or IC_{25} are expressed as a percent effluent in the test medium.
- (3) "Inhibition concentration 25" or "IC₂₅" means the toxicant (effluent) concentration that would cause a twenty-five percent (25%) reduction in a nonquantal biological measurement for the test population. For example, the IC_{25} is the concentration of toxicant (effluent) that would cause a twenty-five percent (25%) reduction in mean young per female or in growth for the test population.
- (4) "No observed effect concentration" or "NOEC" is the highest concentration of toxicant (effluent) to which organisms are exposed in a full life cycle or partial life cycle (short term) test, that causes no observable adverse effects on the test organisms, that is, the highest concentration of toxicant (effluent) in which the values for the observed responses are not statistically significantly different from the controls.

2. Toxicity Reduction Evaluation (TRE) Schedule of Compliance

The development and implementation of a TRE is only required if toxicity is demonstrated in two (2) consecutive tests as described in Part I.E.1.f.(4). The post-TRE toxicity testing requirements in Part I.E.2.c. must also be completed as part of the TRE compliance schedule.

Milestone Dates: See a. through e. below for more detail on the TRE milestone dates.

Requirement	Deadline
Development and Submittal of a TRE Plan	Within 90 days of the date of two (2) consecutive failed toxicity tests.
Initiate a TRE Study	Within 30 days of TRE Plan submittal.
Submit TRE Progress Reports	Every 90 days beginning six (6) months from the date of two (2) consecutive failed toxicity tests.
Post-TRE Toxicity Testing Requirements	Immediately upon completion of the TRE, conduct three (3) consecutive months of toxicity tests with both test species; if no acute or chronic toxicity is shown with any test species, reduce toxicity tests to once annually for the remainder of the permit term. If post-TRE toxicity testing demonstrates toxicity, continue the TRE study.
Submit Final TRE Report	Within 90 days of successfully completing the TRE (including the post-TRE toxicity testing requirements), not to exceed three (3) years from the date that toxicity is initially demonstrated in two (2) consecutive toxicity tests.

a. Development of TRE Plan

Within 90 days of the date of two (2) consecutive failed toxicity tests (i.e. the date of termination of the second test), the permittee must submit plans for an effluent TRE to the Compliance Data Section. The TRE plan must include appropriate measures to characterize the causative toxicants and reduce toxicity in the effluent discharge to levels that demonstrate no toxicity with any test species as described in Part I.E.1.f. Guidance on conducting effluent toxicity reduction evaluations is available from EPA and from the EPA publications listed below:

(1) Methods for Aquatic Toxicity Identification Evaluations:

Phase I Toxicity Characterization Procedures, Second Edition (EPA/600/6-91/003), February 1991.

Phase II Toxicity Identification Procedures for Samples Exhibiting Acute and Chronic Toxicity (EPA/600/R-92/080), September 1993.

Phase III Toxicity Confirmation Procedures for Samples Exhibiting Acute and Chronic Toxicity (EPA/600/R-92/081), September 1993.

- (2) Toxicity Identification Evaluation: Characterization of Chronically Toxic Effluents, Phase I (EPA/600/6-91/005F), May 1992.
- (3) Generalized Methodology for Conducting Industrial Toxicity Reduction Evaluations (TREs) (EPA/600/2-88/070), April 1989.
- (4) Clarifications Regarding Toxicity Reduction and Identification Evaluations in the National Pollutant Discharge Elimination System Program, U.S. EPA, March 27, 2001.

b. Conduct the TRE

Within 30 days after submittal of the TRE plan to the Compliance Data Section, the permittee must initiate the TRE consistent with the TRE plan.

c. Post-TRE Toxicity Testing Requirements

- (1) After completing the TRE, the permittee must conduct monthly post-TRE toxicity tests with the two (2) test species *Ceriodaphnia dubia* and fathead minnow (*Pimephales promelas*) for a period of three (3) consecutive months.
- (2) If the three (3) monthly tests demonstrate no toxicity with any test species as described in Part I.E.1.f., the TRE will be considered successful. Otherwise, the TRE study must be continued.
- (3) The post-TRE toxicity tests must be conducted in accordance with the procedures in Part I.E.1. The results of these tests must be submitted as part of the final TRE Report required under Part I.E.2.d.
- (4) After successful completion of the TRE, the permittee must resume the chronic toxicity tests required in Part I.E.1. The permittee may reduce the number of species tested to only include the species demonstrated to be most sensitive to the toxicity in the effluent. The established starting date for the frequency in Part I.E.1.d. is the first day of the first month following successful completion of the post-TRE toxicity tests.

d. Reporting

- (1) Progress reports must be submitted every 90 days to the Compliance Data Section beginning six (6) months from the date of two (2) consecutive failed toxicity tests. Each TRE progress report must include a listing of proposed activities for the next quarter and a schedule to reduce toxicity in the effluent discharge to acceptable levels through control of the toxicant source or treatment of whole effluent.
- (2) Within 90 days of successfully completing the TRE, including the three (3) consecutive monthly tests required as part of the post-TRE toxicity testing requirements in Part I.E.2.c., the permittee must submit to the Compliance Data Section a final TRE Report that includes the following:
 - (A) A discussion of the TRE results;
 - (B) The starting date established under Part I.E.2.c.(4) for the continuation of the toxicity testing required in Part I.E.1.; and
 - (C) If applicable, the intent to reduce the number of species tested to the one most sensitive to the toxicity in the effluent under Part I.E.2.c.(4).

e. Compliance Date

The permittee must complete items a., b., c. and d. from Part I.E.2. and reduce toxicity in the effluent discharge to acceptable levels as soon as possible, but no later than three (3) years from the date that toxicity is initially demonstrated in two (2) consecutive toxicity tests (i.e. the date of termination of the second test) as described in Part I.E.1.f.(4).

F. REOPENING CLAUSES

This permit may be modified, or alternately, revoked and reissued, after public notice and opportunity for hearing:

1. to comply with any applicable effluent limitation or standard issued or approved under 301(b)(2)(C),(D) and (E), 304 (b)(2), and 307(a)(2) of the Clean Water Act, if the effluent limitation or standard so issued or approved:
 - a. contains different conditions or is otherwise more stringent than any effluent limitation in the permit; or

- b. controls any pollutant not limited in the permit.
2. for any of the causes listed under 327 IAC 5-2-16.
 3. to include whole effluent toxicity limitations or to include limitations for specific toxicants if the results of the biomonitoring and/or the TRE study indicate that such limitations are necessary to meet Indiana Water Quality Standards.
 4. to include a case-specific Limit of Detection (LOD) and/or Limit of Quantitation (LOQ). The permittee must demonstrate that such action is warranted in accordance with the procedures specified under Appendix B, 40 CFR Part 136, using the most sensitive analytical methods approved by EPA under 40 CFR Part 136, or approved by the Commissioner.
 5. to specify the use of a different analytical method if a more sensitive analytical method has been specified in or approved under 40 CFR 136 or approved by the Commissioner to monitor for the presence and amount in the effluent of the pollutant for which the WQBEL is established. The permit shall specify the LOD and LOQ that can be achieved by use of the specified analytical method.

PART II

STANDARD CONDITIONS FOR NPDES PERMITS

A. GENERAL CONDITIONS

1. Duty to Comply

The permittee shall comply with all terms and conditions of this permit in accordance with 327 IAC 5-2-8(1) and all other requirements of 327 IAC 5-2-8. Any permit noncompliance constitutes a violation of the Clean Water Act and IC 13 and is grounds for enforcement action or permit termination, revocation and reissuance, modification, or denial of a permit renewal application.

It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of the permit.

2. Duty to Mitigate

In accordance with 327 IAC 5-2-8(3), the permittee shall take all reasonable steps to minimize or correct any adverse impact to the environment resulting from noncompliance with this permit. During periods of noncompliance, the permittee shall conduct such accelerated or additional monitoring for the affected parameters, as appropriate or as requested by IDEM, to determine the nature and impact of the noncompliance.

3. Duty to Reapply

If the permittee wishes to continue an activity regulated by this permit after the expiration date of this permit, the permittee must obtain and submit an application for renewal of this permit in accordance with 327 IAC 5-2-8(2). It is the permittee's responsibility to obtain and submit the application. In accordance with 327 IAC 5-2-3(c), the owner of the facility or operation from which a discharge of pollutants occurs is responsible for applying for and obtaining the NPDES permit, except where the facility or operation is operated by a person other than an employee of the owner in which case it is the operator's responsibility to apply for and obtain the permit. Pursuant to 327 IAC 5-3-2(a)(2), the application must be submitted at least 180 days before the expiration date of this permit. This deadline may be extended if all of the following occur:

- a. permission is requested in writing before such deadline;
- b. IDEM grants permission to submit the application after the deadline; and
- c. the application is received no later than the permit expiration date.

4. Permit Transfers

In accordance with 327 IAC 5-2-8(4)(D), this permit is nontransferable to any person except in accordance with 327 IAC 5-2-6(c). This permit may be transferred to another person by the permittee, without modification or revocation and reissuance being required under 327 IAC 5-2-16(c)(1) or 16(e)(4), if the following occurs:

- a. the current permittee notified the Commissioner at least thirty (30) days in advance of the proposed transfer date;
- b. a written agreement containing a specific date of transfer of permit responsibility and coverage between the current permittee and the transferee (including acknowledgment that the existing permittee is liable for violations up to that date, and the transferee is liable for violations from that date on) is submitted to the Commissioner;
- c. the transferee certifies in writing to the Commissioner their intent to operate the facility without making such material and substantial alterations or additions to the facility as would significantly change the nature or quantities of pollutants discharged and thus constitute cause for permit modification under 327 IAC 5-2-16(d). However, the Commissioner may allow a temporary transfer of the permit without permit modification for good cause, e.g., to enable the transferee to purge and empty the facility's treatment system prior to making alterations, despite the transferee's intent to make such material and substantial alterations or additions to the facility; and
- d. the Commissioner, within thirty (30) days, does not notify the current permittee and the transferee of the intent to modify, revoke and reissue, or terminate the permit and to require that a new application be filed rather than agreeing to the transfer of the permit.

The Commissioner may require modification or revocation and reissuance of the permit to identify the new permittee and incorporate such other requirements as may be necessary under the Clean Water Act or state law.

5. Permit Actions

- a. In accordance with 327 IAC 5-2-16(b) and 327 IAC 5-2-8(4), this permit may be modified, revoked and reissued, or terminated for cause, including, but not limited to, the following:
 - (1) Violation of any terms or conditions of this permit;
 - (2) Failure of the permittee to disclose fully all relevant facts or misrepresentation of any relevant facts in the application, or during the permit issuance process; or

- (3) A change in any condition that requires either a temporary or a permanent reduction or elimination of any discharge controlled by the permit, e.g., plant closure, termination of discharge by connection to a POTW, a change in state law that requires the reduction or elimination of the discharge, or information indicating that the permitted discharge poses a substantial threat to human health or welfare.
- b. Filing of either of the following items does not stay or suspend any permit condition: (1) a request by the permittee for a permit modification, revocation and reissuance, or termination, or (2) submittal of information specified in Part II.A.3 of the permit including planned changes or anticipated noncompliance.

The permittee shall submit any information that the permittee knows or has reason to believe would constitute cause for modification or revocation and reissuance of the permit at the earliest time such information becomes available, such as plans for physical alterations or additions to the permitted facility that:

- (1) could significantly change the nature of, or increase the quantity of pollutants discharged; or
- (2) the commissioner may request to evaluate whether such cause exists.
- c. In accordance with 327 IAC 5-1-3(a)(5), the permittee must also provide any information reasonably requested by the Commissioner.

6. Property Rights

Pursuant to 327 IAC 5-2-8(6) and 327 IAC 5-2-5(b), the issuance of this permit does not convey any property rights of any sort or any exclusive privileges, nor does it authorize any injury to persons or private property or invasion of other private rights, any infringement of federal, state, or local laws or regulations. The issuance of the permit also does not preempt any duty to obtain any other state, or local assent required by law for the discharge or for the construction or operation of the facility from which a discharge is made.

7. Severability

In accordance with 327 IAC 1-1-3, the provisions of this permit are severable and, if any provision of this permit or the application of any provision of this permit to any person or circumstance is held invalid, the invalidity shall not affect any other provisions or applications of the permit which can be given effect without the invalid provision or application.

8. Oil and Hazardous Substance Liability

Nothing in this permit shall be construed to relieve the permittee from any responsibilities, liabilities, or penalties to which the permittee is or may be subject to under Section 311 of the Clean Water Act.

9. State Laws

Nothing in this permit shall be construed to preclude the institution of any legal action or relieve the permittee from any responsibilities, liabilities, or penalties established pursuant to any applicable state law or regulation under authority preserved by Section 510 of the Clean Water Act or state law.

10. Penalties for Violation of Permit Conditions

Pursuant to IC 13-30-4, a person who violates any provision of this permit, the water pollution control laws; environmental management laws; or a rule or standard adopted by the Environmental Rules Board is liable for a civil penalty not to exceed twenty-five thousand dollars (\$25,000) per day of any violation.

Pursuant to IC 13-30-5, a person who obstructs, delays, resists, prevents, or interferes with (1) the department; or (2) the department's personnel or designated agent in the performance of an inspection or investigation performed under IC 13-14-2-2 commits a class C infraction.

Pursuant to IC 13-30-10-1.5(e), a person who willfully or negligently violates any NPDES permit condition or filing requirement, or any applicable standards or limitations of IC 13-18-3-2.4, IC 13-18-4-5, IC 13-18-12, IC 13-18-14, IC 13-18-15, or IC 13-18-16, commits a Class A misdemeanor.

Pursuant to IC 13-30-10-1.5(i), an offense under IC 13-30-10-1.5(e) is a Level 4 felony if the person knowingly commits the offense and knows that the commission of the offense places another person in imminent danger of death or serious bodily injury. The offense becomes a Level 3 felony if it results in serious bodily injury to any person, and a Level 2 felony if it results in death to any person.

Pursuant to IC 13-30-10-1.5(g), a person who willfully or recklessly violates any applicable standards or limitations of IC 13-18-8 commits a Class B misdemeanor.

Pursuant to IC 13-30-10-1.5(h), a person who willfully or recklessly violates any applicable standards or limitations of IC 13-18-9, IC 13-18-10, or IC 13-18-10.5 commits a Class C misdemeanor.

Pursuant to IC 13-30-10-1, a person who knowingly or intentionally makes any false material statement, representation, or certification in any NPDES form, notice, or report commits a Class B misdemeanor.

11. Penalties for Tampering or Falsification

In accordance with 327 IAC 5-2-8(10), the permittee shall comply with monitoring, recording, and reporting requirements of this permit. The Clean Water Act, as well as IC 13-30-10-1, provides that any person who knowingly or intentionally (a) destroys, alters, conceals, or falsely certifies a record, (b) tampers with, falsifies, or renders inaccurate or inoperative a recording or monitoring device or method, including the data gathered from the device or method, or (c) makes a false material statement or representation in any label, manifest, record, report, or other document; all required to be maintained under the terms of a permit issued by the department commits a Class B misdemeanor.

12. Toxic Pollutants

If any applicable effluent standard or prohibition (including any schedule of compliance specified in such effluent standard or prohibition) is established under Section 307(a) of the Clean Water Act for a toxic pollutant injurious to human health, and that standard or prohibition is more stringent than any limitation for such pollutant in this permit, this permit shall be modified or revoked and reissued to conform to the toxic effluent standard or prohibition in accordance with 327 IAC 5-2-8(5). Effluent standards or prohibitions established under Section 307(a) of the Clean Water Act for toxic pollutants injurious to human health are effective and must be complied with, if applicable to the permittee, within the time provided in the implementing regulations, even absent permit modification.

13. Wastewater treatment plant and certified operators

The permittee shall have the wastewater treatment facilities under the responsible charge of an operator certified by the Commissioner in a classification corresponding to the classification of the wastewater treatment plant as required by IC 13-18-11-11 and 327 IAC 5-22. In order to operate a wastewater treatment plant the operator shall have qualifications as established in 327 IAC 5-22-7.

327 IAC 5-22-10.5(a) provides that a certified operator may be designated as being in responsible charge of more than one (1) wastewater treatment plant, if it can be shown that he will give adequate supervision to all units involved. Adequate supervision means that sufficient time is spent at the plant on a regular basis to assure that the certified operator is knowledgeable of the actual operations and that test reports and results are representative of the actual operations conditions. In accordance with 327 IAC 5-22-3(11), "responsible charge operator" means the person responsible for the overall daily operation, supervision, or management of a wastewater facility.

Pursuant to 327 IAC 5-22-10(4), the permittee shall notify IDEM when there is a change of the person serving as the certified operator in responsible charge of the wastewater treatment facility. The notification shall be made no later than thirty (30) days after a change in the operator.

14. Construction Permit

In accordance with IC 13-14-8-11.6, a discharger is not required to obtain a state permit for the modification or construction of a water pollution treatment or control facility if the discharger has an effective NPDES permit.

If the discharger modifies their existing water pollution treatment or control facility or constructs a new water pollution treatment or control facility for the treatment or control of any new influent pollutant or increased levels of any existing pollutant, then, within thirty (30) days after commencement of operation, the discharger shall file with the Department of Environment Management a notice of installation for the additional pollutant control equipment and a design summary of any modifications.

The notice and design summary shall be sent to the Office of Water Quality, Industrial NPDES Permits Section, 100 North Senate Avenue, Indianapolis, IN 46204-2251.

15. Inspection and Entry

In accordance with 327 IAC 5-2-8(8), the permittee shall allow the Commissioner, or an authorized representative, (including an authorized contractor acting as a representative of the Commissioner) upon the presentation of credentials and other documents as may be required by law, to:

- a. Enter upon the permittee's premises where a regulated facility or activity is located or conducted, or where records must be kept pursuant to the conditions of this permit;
- b. Have access to and copy, at reasonable times, any records that must be kept under the terms and conditions of this permit;
- c. Inspect at reasonable times any facilities, equipment or methods (including monitoring and control equipment), practices, or operations regulated or required pursuant to this permit; and
- d. Sample or monitor at reasonable times, any discharge of pollutants or internal wastestreams for the purposes of evaluating compliance with the permit or as otherwise authorized.

16. New or Increased Discharge of Pollutants

This permit prohibits the permittee from undertaking any action that would result in a new or increased discharge of a bioaccumulative chemical of concern (BCC) or a new or increased permit limit for a regulated pollutant that is not a BCC unless one of the following is completed prior to the commencement of the action:

- a. Information is submitted to the Commissioner demonstrating that the proposed new or increased discharges will not cause a significant lowering of water quality as defined under 327 IAC 2-1.3-2(50). Upon review of this information, the Commissioner may request additional information or may determine that the proposed increase is a significant lowering of water quality and require the submittal of an antidegradation demonstration.
- b. An antidegradation demonstration is submitted to and approved by the Commissioner in accordance with 327 IAC 2-1.3-5 and 327 IAC 2-1.3-6.

B. MANAGEMENT REQUIREMENTS

1. Proper Operation and Maintenance

The permittee shall at all times maintain in good working order and efficiently operate all facilities and systems (and related appurtenances) for the collection and treatment which are installed or used by the permittee and which are necessary for achieving compliance with the terms and conditions of this permit in accordance with 327 IAC 5-2-8(9).

Neither 327 IAC 5-2-8(9), nor this provision, shall be construed to require the operation of installed treatment facilities that are unnecessary for achieving compliance with the terms and conditions of the permit.

2. Bypass of Treatment Facilities

Pursuant to 327 IAC 5-2-8(12), the following are requirements for bypass:

- a. The following definitions:
 - (1) "Bypass" means the intentional diversion of a waste stream from any portion of a treatment facility.
 - (2) "Severe property damage" means substantial physical damage to property, damage to the treatment facilities which would cause them to become inoperable, or substantial and permanent loss of natural resources which can reasonably be expected to occur in the absence of a bypass. Severe property damage does not mean economic loss caused by delays in production.

- b. The permittee may allow a bypass to occur that does not cause a violation of the effluent limitations contained in this permit, but only if it is also for essential maintenance to assure efficient operation. These bypasses are not subject to Part II.B.2.c. and d.
- c. The permittee must provide the Commissioner with the following notice:
 - (1) If the permittee knows or should have known in advance of the need for a bypass (anticipated bypass), it shall submit prior written notice. If possible, such notice shall be provided at least ten (10) days before the date of the bypass for approval by the Commissioner.
 - (2) As required by 327 IAC 5-2-8(11)(C), the permittee shall orally report an unanticipated bypass that exceeds any effluent limitations in the permit within twenty-four (24) hours from the time the permittee becomes aware of such noncompliance. A written submission shall also be provided within five (5) days of the time the permittee becomes aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause; the period of noncompliance, including exact dates and times; and if the cause of noncompliance has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate and prevent recurrence of the noncompliance. If a complete report is submitted by e-mail within 24 hours of the noncompliance, then that e-mail report will satisfy both the oral and written reporting requirement. E-mails should be sent to wwreports@idem.in.gov.
- d. The following provisions are applicable to bypasses:
 - (1) Except as provided by Part II.B.2.b., bypass is prohibited, and the Commissioner may take enforcement action against a permittee for bypass, unless the following occur:
 - (A) Bypass was unavoidable to prevent loss of life, personal injury, or severe property damage.
 - (B) There were no feasible alternatives to the bypass, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of equipment down time. This condition is not satisfied if adequate back-up equipment should have been installed in the exercise of reasonable engineering judgment to prevent a bypass that occurred during normal periods of equipment downtime or preventive maintenance.

- (C) The permittee submitted notices as required under Part II.B.2.c.
- (2) The Commissioner may approve an anticipated bypass, after considering its adverse effects, if the Commissioner determines that it will meet the conditions listed above in Part II.B.2.d.(1). The Commissioner may impose any conditions determined to be necessary to minimize any adverse effects.
- e. Bypasses that result in death or acute injury or illness to animals or humans must be reported in accordance with the "Spill Response and Reporting Requirements" in 327 IAC 2-6.1, including calling 888/233-7745 as soon as possible, but within two (2) hours of discovery. However, under 327 IAC 2-6.1-3(1), when the constituents of the bypass are regulated by this permit, and death or acute injury or illness to animals or humans does not occur, the reporting requirements of 327 IAC 2-6.1 do not apply.

3. Upset Conditions

Pursuant to 327 IAC 5-2-8(13):

- a. "Upset" means an exceptional incident in which there is unintentional and temporary noncompliance with technology-based permit effluent limitations because of factors beyond the reasonable control of the permittee. An upset does not include noncompliance to the extent caused by operational error, improperly designed treatment facilities, inadequate treatment facilities, lack of preventive maintenance, or careless or improper operation.
- b. An upset shall constitute an affirmative defense to an action brought for noncompliance with such technology-based permit effluent limitations if the requirements of Paragraph c of this section, are met.
- c. A permittee who wishes to establish the affirmative defense of upset shall demonstrate, through properly signed, contemporaneous operating logs or other relevant evidence, that:
 - (1) An upset occurred and the permittee has identified the specific cause(s) of the upset;
 - (2) The permitted facility was at the time being properly operated;
 - (3) The permittee complied with any remedial measures required under Part II.A.2; and

- (4) The permittee submitted notice of the upset as required in the "Twenty-Four Hour Reporting Requirements," Part II.C.3, or 327 IAC 2-6.1, whichever is applicable. However, under 327 IAC 2-6.1-3(1), when the constituents of the discharge are regulated by this permit, and death or acute injury or illness to animals or humans does not occur, the reporting requirements of 327 IAC 2-6.1 do not apply.

- d. In any enforcement proceeding, the permittee seeking to establish the occurrence of an upset has the burden of proof pursuant to 40 CFR 122.41(n)(4).

4. Removed Substances

Solids, sludges, filter backwash, or other pollutants removed from or resulting from treatment or control of wastewaters shall be disposed of in a manner such as to prevent any pollutant from such materials from entering waters of the State and to be in compliance with all Indiana statutes and regulations relative to liquid and/or solid waste disposal. The discharge of pollutants in treated wastewater is allowed in compliance with the applicable effluent limitations in Part I. of this permit.

C. REPORTING REQUIREMENTS

1. Planned Changes in Facility or Discharge

Pursuant to 327 IAC 5-2-8(11)(F), the permittee shall give notice to the Commissioner as soon as possible of any planned physical alterations or additions to the permitted facility. In this context, permitted facility refers to a point source discharge, not a wastewater treatment facility. Notice is required only when either of the following applies:

- a. The alteration or addition may meet one of the criteria for determining whether the facility is a new source as defined in 327 IAC 5-1.5.
- b. The alteration or addition could significantly change the nature of, or increase the quantity of, pollutants discharged. This notification applies to pollutants that are subject neither to effluent limitations in Part I.A. nor to notification requirements in Part II.C.9. of this permit.

Following such notice, the permit may be modified to revise existing pollutant limitations and/or to specify and limit any pollutants not previously limited.

2. Monitoring Reports

Pursuant to 327 IAC 5-2-8(10) and 327 IAC 5-2-13 through 15, monitoring results shall be reported at the intervals and in the form specified in "Monthly Reporting", Part I.C.2.

3. Twenty-Four Hour Reporting Requirements

Pursuant to 327 IAC 5-2-8(11)(C), the permittee shall orally report to the Commissioner information on the following types of noncompliance within 24 hours from the time permittee becomes aware of such noncompliance. If the noncompliance meets the requirements of item b (Part II.C.3.b) or 327 IAC 2-6.1, then the report shall be made within those prescribed time frames. However, under 327 IAC 2-6.1-3(1), when the constituents of the discharge that is in noncompliance are regulated by this permit, and death or acute injury or illness to animals or humans does not occur, the reporting requirements of 327 IAC 2-6.1 do not apply.

- a. Any unanticipated bypass which exceeds any effluent limitation in the permit;
- b. Any noncompliance which may pose a significant danger to human health or the environment. Reports under this item shall be made as soon as the permittee becomes aware of the noncomplying circumstances;
- c. Any upset (as defined in Part II.B.3 above) that causes an exceedance of any effluent limitation in the permit; or
- d. Violation of a maximum daily discharge limitation for any of the following toxic pollutants or hazardous substances: chloroform, phenol, toluene

The permittee can make the oral reports by calling (317)232-8670 during regular business hours and asking for the Compliance Data Section or by calling (317) 233-7745 ((888)233-7745 toll free in Indiana) during non-business hours. A written submission shall also be provided within 5 days of the time the permittee becomes aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause; the period of noncompliance, including exact dates and times, and, if the noncompliance has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce and eliminate the noncompliance and prevent its recurrence. The Commissioner may waive the written report on a case-by-case basis if the oral report has been received within 24 hours.

Alternatively the permittee may submit a "Bypass/Overflow Report" (State Form 48373) or a "Noncompliance 24-Hour Notification Report" (State Form 52415), whichever is appropriate, to IDEM at (317) 232-8637 or wwreports@idem.in.gov. If a complete e-mail submittal is sent within 24 hours of the time that the permittee became aware of the occurrence, then the email report will satisfy both the oral and written reporting requirements.

4. Other Compliance/Noncompliance Reporting

Pursuant to 327 IAC 5-2-8(11)(D), the permittee shall report any instance of noncompliance not reported under the "Twenty-Four Hour Reporting Requirements" in Part II.C.3, or any compliance schedules at the time the pertinent Discharge Monitoring Report is submitted. The report shall contain the information specified in Part II.C.3;

The permittee shall also give advance notice to the Commissioner of any planned changes in the permitted facility or activity which may result in noncompliance with permit requirements; and

All reports of compliance or noncompliance with, or any progress reports on, interim and final requirements contained in any compliance schedule of this permit shall be submitted no later than 14 days following each schedule date.

5. Other Information

Pursuant to 327 IAC 5-2-8(11)(E), where the permittee becomes aware of a failure to submit any relevant facts or submitted incorrect information in a permit application or in any report, the permittee shall promptly submit such facts or corrected information to the Commissioner.

6. Signatory Requirements

Pursuant to 327 IAC 5-2-22 and 327 IAC 5-2-8(15):

a. All reports required by the permit and other information requested by the Commissioner shall be signed and certified by a person described below or by a duly authorized representative of that person:

(1) For a corporation: by a responsible corporate officer. A "responsible corporate officer" means either of the following:

(A) A president, secretary, treasurer, any vice president of the corporation in charge of a principal business function, or any other person who performs similar policymaking or decision making functions for the corporation; or

- (B) The manager of one (1) or more manufacturing, production, or operating facilities provided the manager is authorized to make management decisions that govern the operation of the regulated facility including having the explicit or implicit duty to make major capital investment recommendations, and initiating and directing other comprehensive measures to assure long-term environmental compliance with environmental laws and regulations; the manager can ensure that the necessary systems are established or actions taken to gather complete and accurate information for permit application requirements; and where authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.
 - (2) For a partnership or sole proprietorship: by a general partner or the proprietor, respectively; or
 - (3) For a Federal, State, or local governmental body or any agency or political subdivision thereof: by either a principal executive officer or ranking elected official.
- b. A person is a duly authorized representative only if:
 - (1) The authorization is made in writing by a person described above.
 - (2) The authorization specifies either an individual or a position having responsibility for the overall operation of the regulated facility or activity, such as the position of plant manager, operator of a well or a well field, superintendent, or position of equivalent responsibility. (A duly authorized representative may thus be either a named individual or any individual occupying a named position.); and
 - (3) The authorization is submitted to the Commissioner.
- c. Electronic Signatures. If documents described in this section are submitted electronically by or on behalf of the NPDES-regulated facility, any person providing the electronic signature for such documents shall meet all relevant requirements of this section, and shall ensure that all of the relevant requirements of 40 CFR part 3 (including, in all cases, subpart D to part 3) (Cross-Media Electronic Reporting) and 40 CFR part 127 (NPDES Electronic Reporting Requirements) are met for that submission.

- d. Certification. Any person signing a document identified under Part II.C.6., shall make the following certification:

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

7. Availability of Reports

Except for data determined to be confidential under 327 IAC 12.1, all reports prepared in accordance with the terms of this permit shall be available for public inspection at the offices of the Indiana Department of Environmental Management and the Regional Administrator. As required by the Clean Water Act, permit applications, permits, and effluent data shall not be considered confidential.

8. Penalties for Falsification of Reports

IC 13-30 and 327 IAC 5-2-8(15) provides that any person who knowingly makes any false statement, representation, or certification in any record or other document submitted or required to be maintained under this permit, including monitoring reports or reports of compliance, shall, upon conviction, be punished by a fine of not more than \$10,000 per violation, or by imprisonment for not more than 180 days per violation, or by both.

9. Changes in Discharge of Toxic Substances

Pursuant to 327 IAC 5-2-9, the permittee shall notify the Commissioner as soon as it knows or has reason to know:

- a. That any activity has occurred or will occur which would result in the discharge of any toxic pollutant that is not limited in the permit if that discharge will exceed the highest of the following notification levels.
- (1) One hundred micrograms per liter (100 µg/l);
 - (2) Two hundred micrograms per liter (200 µg/l) for acrolein and acrylonitrile; five hundred micrograms per liter (500 µg/l) for 2,4-dinitrophenol and 2-methyl-4,6-dinitrophenol; and one milligram per liter (1 mg/l) for antimony;

- (3) Five (5) times the maximum concentration value reported for that pollutant in the permit application in accordance with 40 CFR 122.21(g)(7); or
 - (4) A notification level established by the Commissioner on a case-by-case basis, either at the Commissioner's own initiative or upon a petition by the permittee. This notification level may exceed the level specified in subdivisions (1), (2), or (3) but may not exceed the level which can be achieved by the technology-based treatment requirements applicable to the permittee under the CWA (see 327 IAC 5-5-2).
- b. That it has begun or expects to begin to use or manufacture, as an intermediate or final product or byproduct, any toxic pollutant that was not reported in the permit application under 40 CFR 122.21(g)(9). However, this subsection b. does not apply to the permittee's use or manufacture of a toxic pollutant solely under research or laboratory conditions.

10. Future Electronic Reporting Requirements

IDEM is currently developing the technology and infrastructure necessary to allow compliance with the EPA Phase 2 e-reporting requirements per 40 CFR 127.16 and to allow electronic reporting of applications, notices, plans, reports, and other information not covered by the federal e-reporting regulations. IDEM will notify the permittee when IDEM's e-reporting system is ready for use for one or more applications, notices, plans, reports, or other information. This IDEM notice will identify the specific applications, notices, plans, reports, or other information that are to be submitted electronically and the permittee will be required to use the IDEM electronic reporting system to submit the identified application(s), notice(s), plan(s), report(s), or other information. See Part I.C.2. of this permit for the current electronic reporting requirements for the submittal of monthly monitoring reports such as the Discharge Monitoring Report (DMR) and the Monthly Monitoring Report (MMR).



**National Pollutant Discharge Elimination System
Fact Sheet for
Elanco US, Inc.
Draft: May 2022
Final: TBD**

Indiana Department of Environmental Management

100 North Senate Avenue
Indianapolis, Indiana 46204
(317) 232-8603
Toll Free (800) 451-6027
www.idem.IN.gov

Permittee:	Elanco US, Inc. Clinton Laboratories 10500 South State Road 63 Clinton, IN 47842-7696 Vermillion County
Existing Permit Information:	Permit Number: IN0002852 Expiration Date: July 31, 2022
Facility Contact:	Jason Morgan, Elanco HSE Director (765)832-4053; Jason.morgan@elancoah.com
Facility Location:	Same as above
Receiving Stream(s):	Wabash River
GLI/Non-GLI:	Non-GLI
Proposed Permit Action:	Renew
Date Application Received:	January 27, 2022
Source Category	NPDES Major – Industrial
Permit Writer:	Nikki Gardner, Senior Environmental Manager (317)232-8707; ngardner@idem.in.gov

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1.0 INTRODUCTION

The Indiana Department of Environmental Management (IDEM) received a National Pollutant Discharge Elimination System (NPDES) Permit application from the permittee on January 27, 2022. In accordance with 327 IAC 5-2-6(a), the current five-year permit was issued with an effective date of August 1, 2017. The permit was subsequently modified on January 30, 2019, to reflect a transfer of ownership. A five-year permit is proposed in accordance with 327 IAC 5-2-6(a).

The Federal Water Pollution Control Act (more commonly known as the Clean Water Act), as amended, (Title 33 of the United States Code (U.S.C.) Section 1251 *et seq.*), requires an NPDES permit for the discharge of pollutants into surface waters. Furthermore, Indiana law requires a permit to control or limit the discharge of any contaminants into state waters or into a publicly owned treatment works. This proposed permit action by IDEM complies with and implements these federal and state requirements.

In accordance with Title 40 of the Code of Federal Regulations (CFR) Sections 124.8 and 124.56, as well as Title 327 of the Indiana Administrative Code (IAC) Article 5-3-8, a Fact Sheet is required for certain NPDES permits. This document fulfills the requirements established in these regulations. This Fact Sheet was prepared in order to document the factors considered in the development of NPDES Permit effluent limitations. The technical basis for the Fact Sheet may consist of evaluations of promulgated effluent guidelines, existing effluent quality, receiving water conditions, Indiana water quality standards-based wasteload allocations (WLA), and other information available to IDEM. Decisions to award variances to Water Quality Standards or promulgated effluent guidelines are justified in the Fact Sheet where necessary.

2.0 FACILITY DESCRIPTION

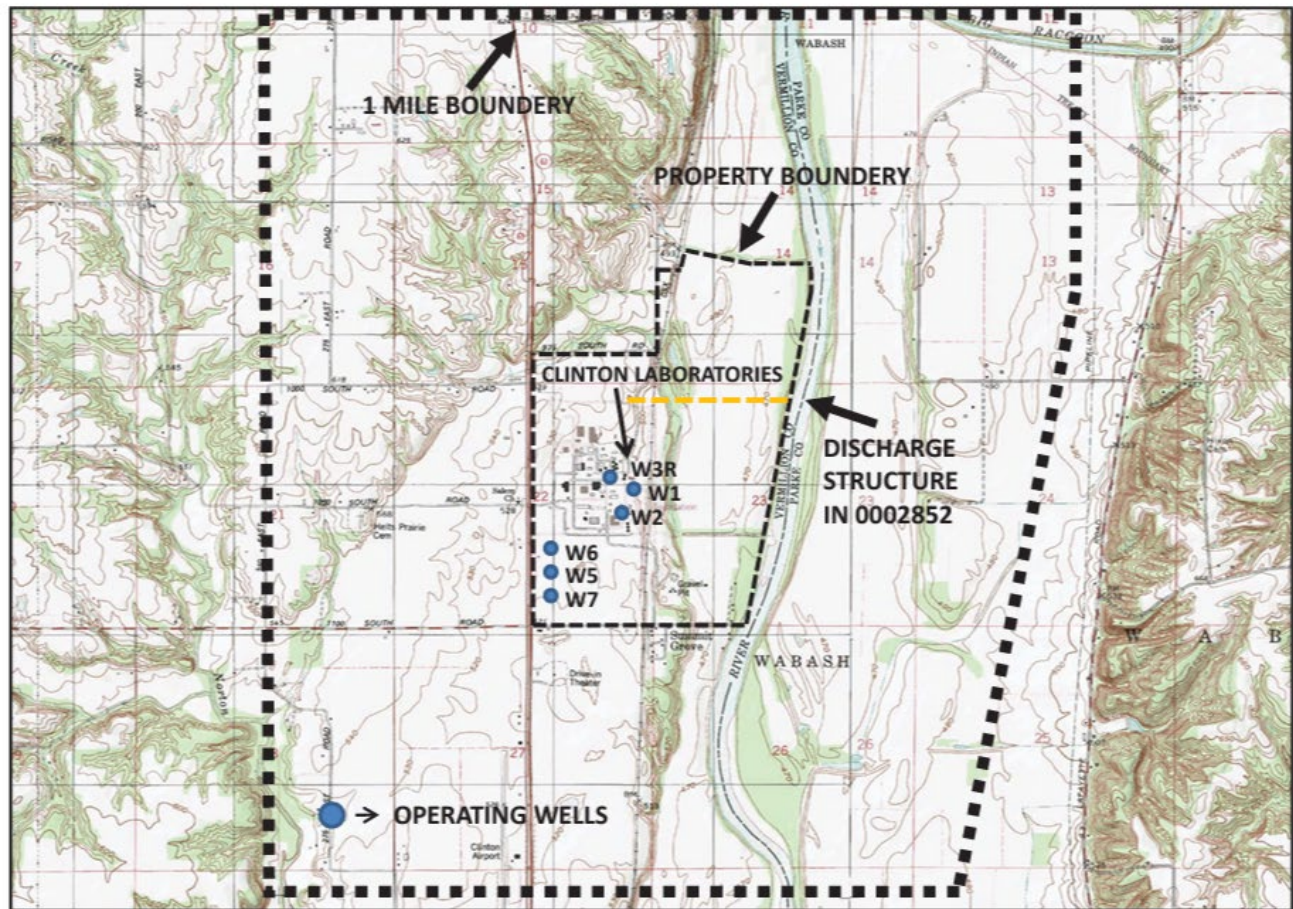
2.1 General

Elanco US, Inc. Clinton Laboratories is classified under Standard Industrial Classification (SIC) Codes 2833 and 2834: Medicinal Chemicals and Botanical Productions and Pharmaceutical Preparations, respectively. The facility manufactures animal health products through fermentation, active ingredient extraction, and formulation/packaging into the final product. The wastewater generated by the fermentation process is subject to the Federal Effluent Guidelines in 40 CFR 439 – Pharmaceutical Manufacturing Category, Subpart A – Fermentation. The facility ferments Narasin and Monensin as active pharmaceutical ingredients (API) for subsequent formulation. The facility currently formulates animal health products and feed ingredients containing the active ingredients Tylosin, Sulfamethazine, Narasin, Nicarbazine, Monensin, Lubabegron, Diclazuril, Spinetoram, Spinosad, and Beta-Mannanase. Only the Monensin and Narasin fermentation processes are relevant with respect to the process wastewater treated in the membrane bioreactor (MBR). The site also includes a variety of support operations such as groundwater wells, solvent storage, solvent recovery, boilers and generators. Source water is a series of groundwater wells with approximate intake of 2.8 MGD.

A map showing the location of the facility has been included as Figure 1.

Figure 1: Facility Location

Fig 1 - TOPOGRAPHIC ONE MILE BOUNDARY MAP OF CLINTON LABORATORIES



10500 South State Road 63
Clinton, IN – Vermillion County

2.2 Outfall Locations

Outfall 001	Latitude: 39° 44' 22" Longitude: -87° 23' 23"
Outfall 101	Latitude: 39° 44' 0.91" Longitude: -87° 23' 34.48"

2.3 Wastewater Treatment

Pharmaceutical effluent flow is approximately 0.17 MGD and consists of wastewater from fermentation, product recovery, and product finishing processes which is passed through distillation strippers. The distillation strippers are part of product recovery and are not considered wastewater treatment. Wastewater from the strippers is cooled and co-treated with 0.02 MGD of sanitary wastewater in the membrane bioreactor. According to the water flow diagram submitted with the permit renewal application, wastewater from fermentation, product recovery and product finishing processes can also be discharged directly to the membrane bioreactor for treatment. The effluent from the membrane bioreactor is disinfected with UV light during disinfection season. Solids from the membrane bioreactor are land applied or sent off-site to a permitted facility for further treatment. The approximate volume discharged from the membrane bioreactor (treated pharmaceutical effluent + treated sanitary wastewater) to Outfall 001 via internal Outfall 101 is 0.19 MGD.

Other discharges to Outfall 001 consist of: 0.91 MGD noncontact cooling water discharges, 0.25 MGD cooling tower blowdown, 0.01 MGD boiler blowdown, 0.12 MGD RO reject water, an unspecified volume of coal pile runoff, and an average of 0.50 MGD of stormwater during storm events. All of these wastestreams are untreated and discharged directly to Outfall 001.

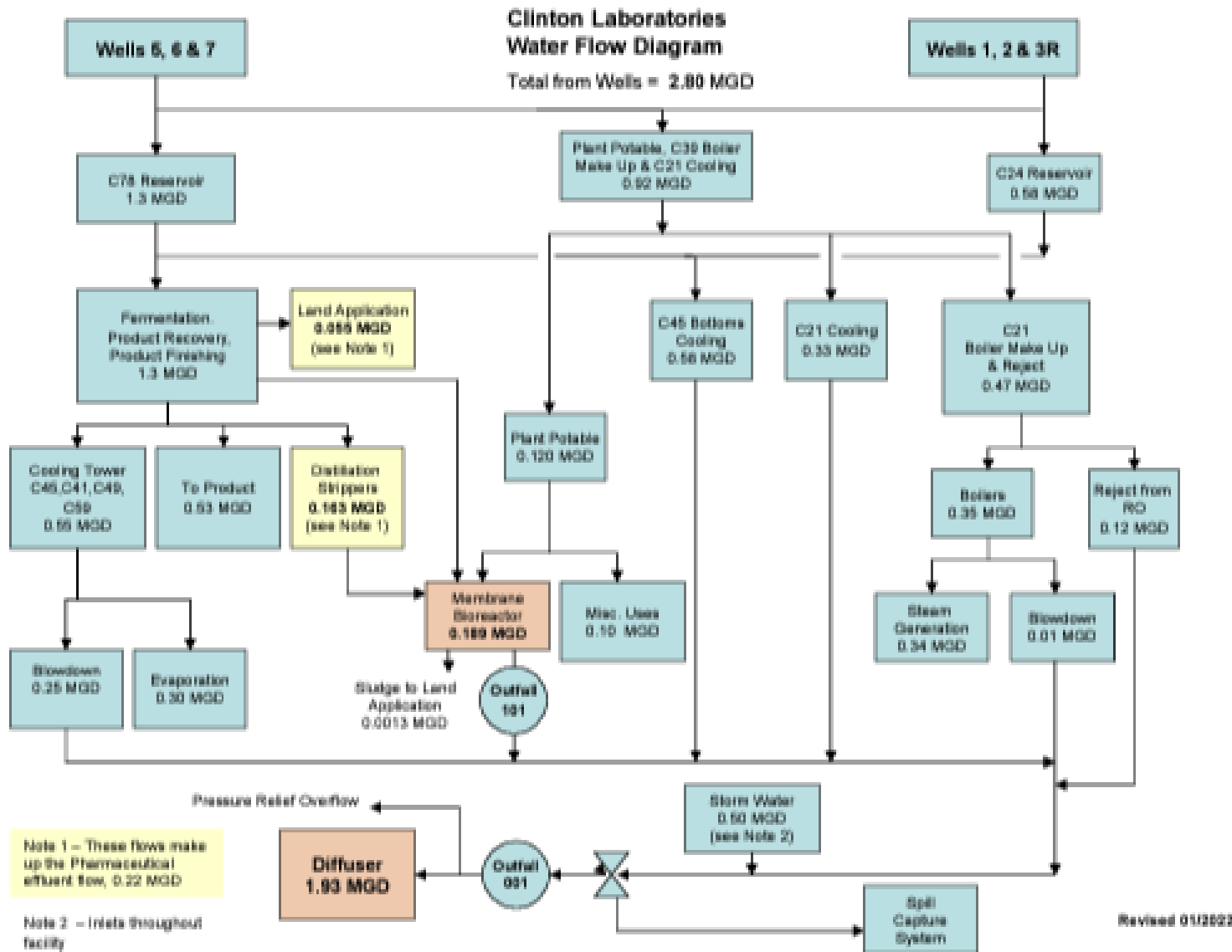
Based on the water flow diagram submitted with the permit renewal application, the wastewater treatment system (membrane bioreactor) has an average discharge of approximately 0.19 MGD and the facility as a whole has an average discharge of approximately 1.93 MGD. Facility wastewater is discharged through a multi-port diffuser at Outfall 001.

Outfall 001: For the purpose of determining the Water Quality-based Effluent Limitations (WQBELs), an estimated flow of 3.4 MGD was used which was based on the highest monthly average flow in the last two years; January 2020 – January 2022.

The permittee shall have the wastewater treatment facilities under the responsible charge of an operator certified by the Commissioner in a classification corresponding to the classification of the wastewater treatment plant as required by IC 13-18-11-11 and 327 IAC 5-22-5. In order to operate a wastewater treatment plant the operator shall have qualifications as established in 327 IAC 5-22-7. No changes have been made at the facility that would affect the wastewater treatment plant classification, therefore, IDEM has retained the permittee's Class C industrial wastewater treatment plant classification. The classification is based on membrane bioreactor treatment.

A Water Balance Diagram has been included as Figure 2.

Figure 2: Water Balance Diagram



2.4 Changes in Operation

As provided in the permit renewal application:

- A. Design Flow – The design flow of the facility increased due to a membrane/cartridge upgrade project and pump impeller replacements. The design flow changed to 0.36 million gallons per day (MGD) from 0.30 MGD.
- B. Streamlined Mercury Variance - The facility has met the mercury limits and therefore no longer has the need for a mercury variance. The Streamlined Mercury Variance (SMV) language in Part III and Pollutant Minimization Program Plan (PMPP) can be removed from the permit.
- C. The coal boiler and associated clarifier have been decommissioned and removed.

2.5 Facility Stormwater

A wastestream consisting of both non-process wastewater and stormwater associated with industrial activity discharges an average of 1.74 MGD to the Wabash River via Outfall 001. These wastestreams are untreated and discharged directly to Outfall 001.

The total area drained is approximately 11,016,220 square feet, with 6,473,641 square feet of impervious surface.

The current permit does not contain any stormwater-specific management or control requirements. Section 5.7 of this Fact Sheet describes the storm water-specific management and control requirements being proposed in this permit.

3.0 PERMIT HISTORY

3.1 Compliance History

A review of this facility's discharge monitoring data was conducted for compliance verification and shows no permit limitation violations at Outfall 001 or Outfall 101 between January 2020 and January 2022. There are no pending or current enforcement actions regarding this NPDES permit.

4.0 LOCATION OF DISCHARGE/RECEIVING WATER USE DESIGNATION

The receiving stream for Outfall 001 is the Wabash River. The $Q_{7,10}$ low flow value of the Wabash River upstream of Outfall 001 is 1090 cfs and shall be capable of supporting a well-balanced, warm water aquatic community and full body contact recreation in accordance with 327 IAC 2-1-3.

The permittee discharges to a waterbody that has been identified as a water of the state that is not within the Great Lakes system. Therefore it is subject to NPDES requirements specific to dischargers not discharging to waters within the Great Lakes system under 327 IAC 2-1 and 327 IAC 5-2-11.1. These rules contain applicable water quality standards and the procedures to calculate and incorporate water quality-based effluent limitations. A Site Map has been included as Figure 3.

Figure 3: Site Map



4.1 Total Maximum Daily Loads (TMDLs)

Section 303(d) of the Clean Water Act requires states to identify waters, through their Section 305(b) water quality assessments, that do not or are not expected to meet applicable water quality standards with federal technology based standards alone. States are also required to develop a priority ranking for these waters taking into account the severity of the pollution and the designated uses of the waters. Once this listing and ranking of impaired waters is completed, the states are required to develop Total Maximum Daily Loads (TMDLs) for these waters in order to achieve compliance with the water quality standards. Indiana's 2020 303(d) List of Impaired Waters was developed in accordance with Indiana's Water Quality Assessment and 303(d) Listing Methodology for Waterbody Impairments and Total Maximum Daily Load Development for the 2020 Cycle.

The Wabash River in the vicinity of Outfall 001 (Assessment Unit INB08G7_04) is on the 2020 303(d) list for PCBs in fish tissue.

TMDLs for the Wabash River in this Assessment Unit are established for E. coli, total phosphorus and nitrate. The EPA, under Section 303(d) of the Clean Water Act, approved the Wabash River Watershed TMDL report on September 22, 2006. A total phosphorus limit has been included in this permit as a result of the total phosphorus TMDL.

5.0 PERMIT LIMITATIONS

5.1 Technology-Based Effluent Limits (TBEL)

TBELs require every individual member of a discharge class or category to operate their water pollution control technologies according to industry-wide standards and accepted engineering practices. TBELs are developed by applying the National Effluent Limitation Guidelines (ELGs) established by EPA for specific industrial categories. Technology-based treatment requirements established pursuant to sections 301(b) and 306 of the CWA represent the minimum level of control that must be imposed in an NPDES permit (327 IAC 5-5-2(a)). In the absence of ELGs, TBELs can also be established on a case-by-case basis using best professional judgment (BPJ) in accordance with 327 IAC 5-2-10 and 327 IAC 5-5 (which implement 40 CFR 122.44, 125.3, and Section 402(a)(1) of the Clean Water Act (CWA)).

BEST PROFESSIONAL JUDGEMENT (BPJ)

EPA develops effluent limitation guidelines (ELGs) for existing industrial and commercial activities as directed in the 1972 amendments of the Clean Water Act. The federal effluent limitation guidelines and standards are located at 40 CFR 403 through 471, inclusive, and are incorporated into Indiana law at 327 IAC 5-2-1.5. In Indiana, NPDES permits are required to ensure compliance with these federal effluent limitation guidelines and standards under 327 IAC 5-2-10(a)(1), 327 IAC 5-2-10(a)(2), and 327 IAC 5-5-2. ELGs are technology-based effluent limitations (TBELs). The intent of a TBEL is to require a minimum level of treatment for industrial point sources based on currently available treatment technologies.

Where EPA has not yet developed guidelines for a particular industry, best professional judgment (BPJ) may be used to develop case-by-case technology-based permit limitations under 327 IAC 5-5-2 and 5-2-10 (see also 40 CFR 122.44 and 125.3, and Section 402(a)(1) of the Clean Water Act). Therefore, as provided by law, IDEM may establish TBELs in the proposed permit utilizing BPJ to meet the requirements of Best Conventional Pollutant Control Technology and Best Available Technology Economically Achievable (BCT/BAT).

EFFLUENT LIMITATION GUIDELINES (ELGS)

The applicable technology-based standards for the Elanco US, Inc. Clinton Laboratories facility are contained in 40 CFR 439 Subpart A – Pharmaceutical Manufacturing Point Source Category, Fermentation Products. These limits are applied at internal Outfall 101.

Applicable ELG Subparts

Outfall	Subpart	Description
101	439.12	BPT limitations
	439.13	BCT limitations
	439.14	BAT limitations

Mass effluent limitations were calculated using 0.2 MGD; which is the long term average flow for Internal Outfall 101 provided in Form 2C. Internal Outfall 101 is the combination of process effluent flow plus allowable non-process flow from sanitary wastewater. These flows combine prior to treatment in the membrane bioreactor and meet the allowable non-process flow criteria. According to EPA's Permit Guidance Document: Pharmaceutical Manufacturing Point Source Category (January 2006, EPA 821-F-05-006), when calculating allowable mass discharges, the permit writer should consider only the sources of process wastewater discharge and only sources of non-process wastewater such that the percentage of non-process wastewaters in the total regulated flow is no more than 25%. TBEL calculations are provided in Appendix A to the Fact Sheet.

5.2 Water Quality-Based Effluent Limits

WQBELs are designed to be protective of the beneficial uses of the receiving water and are independent of the available treatment technology. The WQBELs for this facility are based on water quality criteria in 327 IAC 2-1-6 or developed under the procedures described in 327 IAC 2-1-8.2 through 8.7 and 327 IAC 2-1-8.9, and implementation procedures in 327 IAC 5. Limitations are required for any parameter which has the reasonable potential to exceed (RPE) a water quality criterion as determined using the procedures under 327 IAC 5-2-11.1(h).

The facility discharges through a submerged high-rate diffuser outfall structure and has been granted an alternate acute mixing zone (AMZ) with an associated dilution factor of 29.2. The AMZ review for the existing diffuser is provided in a report dated October 27, 2008. The approved AMZ for the existing diffuser was incorporated into a permit modification issued June 3, 2009.

Since 2009, the discharge flow from the facility has remained consistent with the maximum monthly average flow of 4 mgd considered in the AMZ approval. Therefore, the dilution factor of 29.2 has been retained for the reasonable potential analysis for ammonia (as N), and calculation of WQBELs for total residual chlorine and acute TRE triggers for WET in support of the permit renewal in 2022 (see WLA002637 included as Appendix B.)

5.3 Effluent Limitations and Monitoring Requirements by Outfall

Under 327 IAC 5-2-10(a) (see also 40 CFR 122.44), NPDES permit requirements are technology-based effluent limitations and standards (including technology-based effluent limitations (TBELs) based on federal effluent limitations guidelines or developed on a case-by-case basis using best professional judgment (BPJ), where applicable), water quality standards-based, or based on other more stringent requirements. The decision to limit or monitor the parameters contained in this permit is based on information contained in the permittee's NPDES application and other available information relating to the facility and the receiving waterbody as well as the applicable federal effluent limitations guidelines. In addition, when renewing a permit, the existing permit limits, the antibacksliding requirements under 327 IAC 5-2-10(a)(11), and the antidegradation requirements under 327 IAC 2-1.3 must be considered.

5.3.1 All External Outfalls (Outfall 001)

Narrative Water Quality Based Limits

The narrative water quality criteria contained under 327 IAC 2-1-6(a)(1) and (2) have been included in this permit to ensure that these minimum water quality conditions are met.

Flow

The effluent flow is to be monitored in accordance with 327 IAC 5-2-13(a)(2). Monitoring is to be conducted daily and the 24-hour total reported.

5.3.2 Final Outfall 001

pH

Discharges to waters of the state are limited to the range of 6.0-9.0 s.u., in accordance with 327 IAC 2-1-6(b)(2). Monitoring is to be conducted 1 X daily by grab sampling.

Temperature

Due to the presence of noncontact cooling water and cooling tower blowdown in the discharge at Outfall 001, temperature monitoring has been retained from the previous permit. Temperature monitoring is important to ensure the proper operation of the cooling tower system and to monitor the thermal discharge to the receiving stream. Monitoring is to be conducted 1 X weekly by grab sampling.

Oil and Grease (O & G)

Oil & Grease is commonly limited in permits containing noncontact cooling water. In accordance with both 40 CFR 125.3 and 327 IAC 5-5-2, technology-based treatment requirements may be imposed through the application of effluent limitation guidelines (ELG) or on a case-by-case basis. Where ELGs only apply to certain aspects of or certain pollutants in a discharger's operation, other aspects or activities are subject to regulation on a case-by-case basis in order to carry out the provisions of the CWA. Noncontact cooling water is not limited by the ELG which regulates this facility; 40 CFR 439 – Pharmaceutical Manufacturing Category, Subpart A – Fermentation. Therefore, the effluent limitations found in ING250000 are applied. The oil & grease limit of quantitation (LOQ) of 5 mg/l is used to determine the presence of oil & grease in the discharge. When noncontact cooling water systems are properly operated and maintained, oil & grease should not be present in the effluent. Therefore, if oil & grease is measured in the effluent in detectable quantities, the source of such discharge is to be investigated and eliminated. Monitoring is to be conducted 1 X weekly by grab sampling.

Total Residual Chlorine (TRC)

The permittee currently uses water treatment additives containing chlorine which may be present in the discharge. An outdated flow value was used to calculate TRC limits in the current permit.

As part of this permit renewal, a new WLA report was drafted. See WLA002637 (Appendix B). The limits have been recalculated using the current flow, current $Q_{7,10}$ of the receiving stream and diffuser-based dilution factor of 29.2. The limitations are now 0.28 mg/l monthly average and 0.55 mg/l daily maximum. Monitoring is to be conducted 1 X weekly by grab sampling.

BOD₅

BOD₅ is subject to the technology-based standards contained in 40 CFR 439 Subpart A – Pharmaceutical Manufacturing Point Source Category, Fermentation Products. The TBELs are included as Appendix B.

In previous permits, the BOD₅ TBELs were applied to the commingled wastestreams discharging at final Outfall 001. The TBELs are applicable only to pharmaceutical process and allowable non-process flows, therefore, this permit proposes to move the BOD₅ TBELs to internal Outfall 101 where the pharmaceutical process and allowable non-process flows are discharged, prior to commingling with dilution flows.

A WLA for the facility completed on July 5, 1991, calculated a monthly average loading limit of 5362 lbs/day and a daily maximum loading limit of 10,724 lbs/day for this facility. The previous BOD₅ effluent limitations applied at Outfall 001 (634 lbs/day monthly average and 1,525 lbs/day daily maximum) and the BOD₅ effluent limitations proposed for internal Outfall 101 (66 lbs/day monthly average and 159 lbs/day daily maximum) are well below the WLA loading limit and are protective of water quality.

BOD₅ will continue to be monitored at Outfall 001 and the data used to monitor compliance with the WQBELs. Monitoring is to be conducted 1 X weekly by 24-hour composite sampling.

Total Suspended Solids (TSS)

TSS is subject to the technology-based standards contained in 40 CFR 439 Subpart A – Pharmaceutical Manufacturing Point Source Category, Fermentation Products. The TBELs are included as Appendix B.

In previous permits, the TSS TBELs were applied to the commingled wastestreams discharging at final Outfall 001. When calculating the prior TSS limits at Outfall 001, the permittee requested additional TSS allocations for contributions from additional sources such as cooling tower blowdown, boiler blowdown, RO reject and stormwater. However, IDEM believes technical mistakes were made in developing the additional allocations for stormwater (e.g., rainfall events of one inch or greater weren't considered in the calculation of monthly average effluent limitations) and sample data for specific wastestreams wasn't available.

Additionally, with regard to the technology-based standards contained in 40 CFR 439 Subpart A, the maximum monthly average limitation for TSS, expressed as mass loading per day, must be calculated as 1.7 times the BOD₅ limitation determined in accordance with 40 CFR 439.12(a). In accordance with 40 CFR 439.12(a), the maximum monthly average limitation for BOD₅, expressed as mass loading per day, must reflect not less than 90 percent reduction in the long-term average daily BOD₅ load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0. The long-term average daily BOD₅ load of the raw process wastewater (i.e., the base number to which the percent reduction is applied) is defined as the average daily BOD₅ load during any calendar month, over 12 consecutive months within the most recent 36 months and must include one or more periods during which production was at a maximum. In previous permits, an accurate long-term average daily BOD₅ load of the raw process wastewater was not available for use in calculating the BOD₅ and TSS limits. That data was collected for internal Outfall 101 during the 2017-2022 permit term and submitted on the DMR/MMR as well as with the permit renewal application. Using the correct long-term average BOD₅, the TSS TBELs have been calculated and applied at internal Outfall 101. The limits are more stringent than those previously calculated and applied at Outfall 001.

IDEM proposes to retain the current TSS monitoring frequency of 1 X weekly by 24-hour composite sampling. In the absence of information necessary to calculate TSS limits contributed by all wastestreams present in the discharge from Outfall 001, IDEM proposes to apply non-numeric technology-based effluent limits in lieu of numeric limits. The permittee will be required to develop and implement control measures and Best Management Practices (BMPs), and these non-numeric technology-based requirements must be documented in a Storm Water Pollution Prevention Plan (SWPPP). TSS data collected at Outfall 001 be a valuable tool for monitoring the effectiveness of the SWPPP.

COD

COD is subject to the technology-based standards contained in 40 CFR 439 Subpart A – Pharmaceutical Manufacturing Point Source Category, Fermentation Products. The TBELs are included as Appendix B. In previous permits, the COD TBELs were applied to the commingled wastestreams discharging at final Outfall 001. The TBELs are applicable only to pharmaceutical process and allowable non-process flows, therefore, this permit proposes to move the COD TBELs to internal Outfall 101 where the pharmaceutical process and allowable non-process flows are discharged, prior to commingling with dilution flows.

Indiana has not developed water quality criteria for COD; however, COD will continue to be monitored at Outfall 001 because limits will now be applied at an internal outfall. Monitoring is to be conducted 1 X weekly by 24-hour composite sampling.

Ammonia (as N)

Ammonia (as N) is subject to the technology-based standards contained in 40 CFR 439 Subpart A – Pharmaceutical Manufacturing Point Source Category, Fermentation Products. The TBELs are included as Appendix B. In previous permits, the ammonia TBELs were applied to the commingled wastestreams discharging at final Outfall 001. The TBELs are applicable only to pharmaceutical process and allowable non-process flows, therefore, this permit proposes to move the ammonia TBELs to internal Outfall 101 where the pharmaceutical process and allowable non-process flows are discharged, prior to commingling with dilution flows.

As part of this permit renewal, WLA002637 was completed (see Appendix B). The results of the RPE analysis show that ammonia (as N) does not have RPE, therefore, water quality-based effluent limitations are not required at the final outfall.

Ammonia (as N) will continue to be monitored at Outfall 001 and the data used to monitor compliance with the WQBELs. Monitoring is to be conducted 1 X weekly by 24-hour composite sampling.

Total Phosphorus

Excessive phosphorus in wastewater can result in harmful algal blooms that negatively impact fish habitat, cause fish kills, lower dissolved oxygen, and pose public health concerns related to increased exposure to toxic microbes. The effects of nutrient pollution can be observed both in local waters as well as downstream waters.

A TMDL for the Wabash River has been developed for E. coli, nutrients (total phosphorus and nitrates), impaired biotic communities, dissolved oxygen, and pH. U.S. EPA under Section 303(d) of the Clean Water Act approved the Wabash River Watershed TMDL report on September 22, 2006 for 162 impairments. TMDL reports identify and evaluate water quality problems in impaired water bodies and propose solutions to bring those waters into attainment with water quality standards.

The TMDL for total phosphorus was based upon NPDES facilities meeting a total phosphorus limit of 1.0 mg/l. Therefore, a total phosphorus limit of 1.0 mg/l monthly average has been included in this permit. A reporting requirement for daily maximum concentration (mg/l) has also been included. Monitoring is to be conducted 2 X monthly by 24-hour composite sampling.

Mercury

In 2012, IDEM determined mercury in the discharge had reasonable potential to exceed (RPE) water quality standards. The permittee subsequently requested and was granted a Streamlined Mercury Variance (SMV). In 2017, the permittee requested renewal of the SMV, which was granted.

In the 2022 permit renewal application, the permittee stated that the facility “has met the mercury limits and therefore no longer has the need for a mercury variance. The Streamlined Mercury Variance (SMV) language in Part III and Pollutant Minimization Program Plan (PMPP) can be removed from the permit.”

As part of this permit renewal, WLA002637 was completed (see Appendix B). Mercury was evaluated for RPE. For mercury RPE evaluations, data for the current permit term are typically used. However, the facility identified and eliminated a significant source in March 2019. Therefore, data for the period beginning April 2019 were considered to be representative and were used in the reasonable potential analysis. The results of the analysis show that the discharge does not have RPE.

Due to the source and nature of the discharge and historical presence of mercury, IDEM proposes to retain mercury monitoring. However, a reduction in sample frequency is proposed based on the RPE result. Grab sampling must be completed 1 x annually using EPA Test Method 1631, Method E.

5.3.3 Internal Outfall 101

E. coli

The E. coli limitations have been retained from the previous permit. In accordance with 327 IAC 2-1-6(d), during the disinfection season E. coli bacteria shall not exceed 125 per 100 ml as a geometric mean (monthly average) and 235 per 100ml in any one sample (daily maximum). The disinfection season is defined as April 1 through October 31, annually. The permittee uses UV light for disinfection. In the current permit, the sample frequency is 5 X monthly. The permittee requested the frequency change to 1 X weekly to reduce sample scheduling errors. IDEM has accepted this request.

BOD₅

BOD₅ is subject to the technology-based standards contained in 40 CFR 439 Subpart A – Pharmaceutical Manufacturing Point Source Category, Fermentation Products. In accordance with 40 CFR 439.12(a), the maximum monthly average limitation for BOD₅, expressed as mass loading (lbs., kg) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD₅ load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

The long-term average daily BOD₅ load of the raw process wastewater (i.e., the base number to which the percent reduction is applied) is defined as the average daily BOD₅ load during any calendar month, over 12 consecutive months within the most recent 36 months and must include one or more periods during which production was at a maximum.

To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD₅ load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or separate disposal or reuse. These residual amounts may be included in the calculation of the average influent BOD₅ loading. The practices of recovery, and/or separate disposal or reuse include: physical separation and removal of separable mycelia; recovery of solvents from waste streams; incineration of concentrated solvent wastestreams (including tar still bottoms); and concentration of broth for disposal other than to the treatment system. This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD₅ may be achieved by any of several, or a combination, of these practices.

The previous permit included a requirement to report BOD₅ influent data (raw/untreated process wastewater) so that an accurate long-term average could be determined and used to calculate limits. The requirement to report BOD₅ influent data will be retained in the renewed permit, as this remains the federally required mechanism for determining limits. TBELs are included as Appendix B. Monitoring is to be conducted 2 X monthly by 24-hour composite sampling.

Total Suspended Solids (TSS)

TSS is subject to the technology-based standards contained in 40 CFR 439 Subpart A – Pharmaceutical Manufacturing Point Source Category, Fermentation Products. In accordance with 40 CFR 439.12(b), the maximum monthly average limitation for TSS, expressed as mass loading (lbs., kg) per day, were calculated as 1.7 times the BOD₅ limitation determined in accordance with 40 CFR 439.12(a). TBELs are included as Appendix B. Monitoring is to be conducted 2 X monthly by 24-hour composite sampling.

COD

COD is subject to the technology-based standards contained in 40 CFR 439 Subpart A – Pharmaceutical Manufacturing Point Source Category, Fermentation Products. In accordance with 40 CFR 439.12(d), if the maximum monthly average COD concentration in 40 CFR 439.12(c) is higher than a concentration value reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then the monthly average limitation for COD corresponding to the lower concentration value must be applied.

The monthly average value in 40 CFR 439.12(c) is 856 mg/l. The monthly average value calculated in accordance with 40 CFR 439.12(d) is 273 mg/l. Therefore, the calculated value must be applied to the discharge.

The previous permit included a requirement to report COD influent data (raw/untreated process wastewater) so that an accurate long-term average could be determined and used to calculate limits. The calculated limits are then compared to the limits in 40 CFR 439.12(c), and the more stringent applied. The requirement to report COD influent data will be retained in the renewed permit, as this remains the federally required mechanism for determining limits. TBELs are included as Appendix B. Monitoring is to be conducted 2 X monthly by 24-hour composite sampling.

Ammonia (as N), Acetone, Amyl alcohol, Chloroform, Ethanol, Isopropanol, Methanol, Methylene chloride, Phenol, and Toluene

These pollutants are subject to the technology-based standards contained in 40 CFR 439 Subpart A – Pharmaceutical Manufacturing Point Source Category, Fermentation Products. Limitations have been calculated in accordance with 40 CFR 439.14. TBELs are included as Appendix B. Monitoring frequencies will be retained with the exception of ammonia (as N). Ammonia (as N) will be monitored 2 X monthly by 24-hour composite.

Acetonitrile, Benzene, n-Butyl acetate, Chlorobenzene, o-Dichlorobenzene, 1,2-Dichloroethane, Diethyl amine, Dimethyl sulfoxide, Ethyl acetate, n-Hexane, Isobutyraldehyde, Isopropyl acetate, Isopropyl ether, Methyl cellosolve, Methyl formate, 4-Methyl-2-pentanone (MIBK), Tetrahydrofuran, Triethyl amine, Xylenes, n-Amyl acetate, n-Heptane

These pollutants are subject to the technology-based standards contained in 40 CFR 439 Subpart A – Pharmaceutical Manufacturing Point Source Category, Fermentation Products.

In accordance with 40 CFR 439.2, permit limits and compliance monitoring are not required for regulated pollutants that are neither used nor generated at the facility. A determination that regulated pollutants are neither used nor generated at the facility should be based on a review of all raw materials in use, and an assessment of the process chemistry, products and by-products resulting from each of the manufacturing processes. This determination must be submitted with each permit application for

approval by IDEM, reconfirmed by an annual chemical analysis of wastewater from Internal Outfall 101, and measurement of non-detect values for each regulated pollutant.

The permittee has certified that the pollutants above are not used in any of Clinton Laboratories processes nor are they generated by the pharmaceutical processes. A review of data submitted to IDEM confirmed that measurements of these pollutants during the last five (5) years have been non-detects. Therefore, IDEM proposes to continue annual monitoring.

Factors resulting in a determination that regulated pollutants are neither used nor generated at the facility must be maintained in the facility's permit records with the discharge monitoring reports and must be available to regulatory authorities upon request. Additionally, the permit may be modified, or alternately, revoked and reissued, after public notice and opportunity for hearing to include additional monitoring and/or limitations if annual monitoring identifies that a regulated pollutant, previously certified as a non-use regulated chemical, is being discharged. Monitoring is to be conducted 1 X annually by 24-hour composite sampling.

Chloroform

Chloroform is subject to the technology-based standards contained in 40 CFR 439 Subpart A – Pharmaceutical Manufacturing Point Source Category, Fermentation Products. In the previous permit, additional allocations were granted for the presence of sanitary wastewater. Sanitary wastewater flow is already included in the calculation of effluent limitations for this outfall (0.17 MGD treated pharmaceutical effluent + 0.02 MGD treated sanitary wastewater). Data reviewed shows that the facility can meet the limits as calculated for this permit renewal. Therefore, no additional allocations for chloroform are proposed. TBELs are included as Appendix B. The monitoring frequency will be retained from the previous permit.

Total Cyanide

In accordance with 40 CFR 439.12(g), compliance with the total cyanide limitations may be achieved by certifying to the permit issuing authority that the facility's manufacturing processes neither use nor generate cyanide. The permittee has certified that cyanide is not used in or generated in the pharmaceutical fermentation processes; therefore, no numeric limitation has been applied to the pharmaceutical discharges from this facility.

5.4 Whole Effluent Toxicity (WET) Testing

Whole effluent toxicity (WET) test requirements are included in the NPDES permit to monitor compliance with the narrative water quality criteria under 327 IAC 2-1-6(a)(1)(E) and (a)(2). 327 IAC 2-1-6(a)(1)(E) requires all surface waters at all times and all places, including the mixing zone, to be free from substances, materials, etc. which are in amounts sufficient to be acutely toxic to or to otherwise severely injure or kill aquatic life, other animals, plants, or humans. 327 IAC 2-1-6(2) requires that all waters outside the mixing zone be free of substances in concentrations that on the basis of available scientific data are believed to be sufficient to injure, be chronically toxic to, or be carcinogenic, mutagenic, or teratogenic to humans, animals, aquatic life, or plants. In addition, under 327 IAC 5-2-11.1(h), IDEM is required to determine whether the discharge causes, or has the reasonable potential to cause or contribute to a violation of these narrative water quality criteria.

During the previous permit term, the effluent did not demonstrate acute or chronic toxicity and the permittee was not required to conduct a Toxicity Identification Evaluation (TIE) or Toxicity Reduction Evaluation (TRE).

Given the source and nature of the discharge, the WET Testing frequency of 1 X annually will be retained. As part of WLA002637 (see Appendix B), acute and chronic toxicity values were recalculated using the current flow, current $Q_{7,10}$ of the receiving stream and diffuser-based dilution factor of 29.2. The acute value remains 8.8 TUa and the chronic value is now 53 TUC. These compliance values are proposed in the permit. These TUa and TUC values do not represent effluent limitations, but rather exceedance of these values results in a demonstration of toxicity that triggers additional action and reporting by the permittee.

The whole effluent toxicity testing requirement does not negate the requirement to submit a water treatment additive (WTA) application and/or worksheet for replacement or new additives/chemicals proposed for use at the site.

5.5 Antibacksliding

Indiana's prohibitions on backsliding under 327 IAC 5-2-10(a)(11) are applicable to BPJ case-by-case technology-based effluent limitations, when proposed to be increased based on subsequently promulgated effluent guidelines under Section 304(b) of the CWA, and limitations based on Indiana water quality standards or treatment standards (327 IAC 5-10). Prohibitions on other types of backsliding (e.g., backsliding from limitations derived from effluent guidelines, from existing case-by-case limitations to new case-by-case limitations, and from conditions such as monitoring requirements that are not effluent limitations) are covered under federal regulation at 40 CFR 122.44(l)(1).

Under 5-2-10(a)(11), unless an exception under 10(a)(11)(B) applies, a permit may not be renewed, reissued or modified to contain effluent limitations that are less stringent than the comparable effluent limitations in the previous permit. For effluent limitations based on Indiana water quality or treatment standards, less stringent effluent limitations may also be allowed if they are in compliance with Section 303(d)(4) of the CWA. Under 40 CFR 122.44(l)(1), a permit

may not be renewed or reissued to contain less stringent interim effluent limitations, standards or conditions than the final effluent limitations, standards or conditions in the previous permit unless the circumstances on which the previous permit was based have materially and substantially changed since the time the permit was issued and would constitute cause for permit modification or revocation and reissuance under 40 CFR 122.62.

The proposed permit includes effluent limitations based on water quality standards, existing effluent guidelines, and BPJ case-by-case technology-based effluent limitations. Under 40 CFR 122.62(a)(15), a cause for modification exists to correct technical mistakes, such as errors in calculation, or mistaken interpretations of law made in determining permit conditions. IDEM believes technical mistakes were made in developing TSS limits for Outfall 001 during previous permit terms. Errors in calculations were made in developing the TSS allocations for stormwater (e.g., rainfall events of one inch or greater weren't considered in the calculation of monthly average effluent limitations) and sample data for specific wastestreams wasn't available. Therefore, as part of this permit renewal, IDEM proposes to apply more stringent ELG-based TSS limits at internal Outfall 101 and apply non-numeric limits in lieu of numeric limits at final Outfall 001.

BOD₅, ammonia (as N) and COD limitations are proposed to be moved from final Outfall 001 to internal Outfall 101. The TBELs apply to the pharmaceutical process discharge rather than the commingled (dilution) wastestreams present at the final outfall. The BOD₅ and ammonia TBELs proposed to be applied at internal Outfall 101 are more stringent than the WQBELs applicable to the final outfall. The discharge from Outfall 001 does not show RPE for BOD₅ or ammonia. The COD TBELs proposed to be applied at internal Outfall 101 are more stringent than the TBELs currently applied at the final Outfall 001. Indiana has not developed water quality criteria for COD, therefore, WQBELs can't be calculated at this time.

The proposed effluent limitations do not violate backsliding requirements; therefore, backsliding is not an issue in this permit renewal.

5.6 Antidegradation

Indiana's Antidegradation Standards and Implementation procedures are outlined in 327 IAC 2-1.3. The antidegradation standards established by 327 IAC 2-1.3-3 apply to all surface waters of the state. The permittee is prohibited from undertaking any deliberate action that would result in a new or increased discharge of a bioaccumulative chemical of concern (BCC) or a new or increased permit limit for a regulated pollutant that is not a BCC unless information is submitted to the commissioner demonstrating that the proposed new or increased discharge will not cause a significant lowering of water quality, or an antidegradation demonstration submitted and approved in accordance 327 IAC 2-1.3-5 and 2-1.3-6.

The NPDES permit does not propose to establish a new or increased loading of a regulated pollutant; therefore, the Antidegradation Implementation Procedures in 327 IAC 2-1.3-5 and 2-1.3-6 do not apply to the permitted discharge.

5.7 Stormwater

Under 327 IAC 5-4-6(d), if an individual permit is required under 327 IAC 5-4-6(a) for discharges consisting entirely of stormwater, or if an individual permit is required under 327 IAC 5-2-2 that includes discharge of commingled stormwater associated with industrial activity, IDEM may consider the following in determining the requirements to be contained in the permit:

- (1) The nature of the discharges and activities occurring at the site or facility.
- (2) Information relevant to the potential impact on water quality.
- (3) The requirements found in the following: (A) 327 IAC 5-2, (B) 327 IAC 5-5, (C) 327 IAC 5-9, and (D) 327 IAC 15-6.
- (4) "Interim Permitting Approach for Water Quality-Based Effluent Limitations in Stormwater Permits", EPA 833-D-96-001, September 1, 1996, available from U.S. EPA, National Service Center for Environmental Publications at <https://www.epa.gov/nscep> or from IDEM.

According to 40 CFR 122.26(b)(14) and 327 IAC 15-6-2, facilities classified under Standard Industrial Classification 283 are considered to be engaging in "industrial activity" for purposes of 40 CFR 122.26(b). Therefore, the permittee is required to have all stormwater discharges associated with industrial activity permitted. Treatment for stormwater discharges associated with industrial activities is required to meet, at a minimum, best available technology economically achievable/best conventional pollutant control technology (BAT/BCT) requirements. EPA has determined that non-numeric technology-based effluent limits have been determined to be equal to the best practicable technology (BPT) or BAT/BCT for stormwater associated with industrial activity.

Stormwater associated with industrial activity must also be assessed to ensure compliance with all water quality standards. Effective implementation of the non-numeric technology-based requirements should, in most cases, control discharges as necessary to meet applicable water quality standards.

Additionally, IDEM has determined that with the appropriate implementation of the required control measures and Best Management Practices (BMPs) found in Part I.D. of the permit, the discharge of stormwater associated with industrial activity from this facility will meet applicable water quality standards and will not cause a significant lowering of water quality. Therefore, the stormwater discharge is in compliance with the antidegradation standards found in 327 IAC 2-1.3-3, and pursuant to 327 IAC 2-1.3-4(a)(5), an antidegradation demonstration is not required.

The permittee will be required to develop and implement a Storm Water Pollution Prevention Plan (SWPPP) as outlined in Part I.D. of the permit. These requirements in Part I.D. conform to the requirements set forth in 327 IAC 15-6-7 and 7.5 as authorized by 327 IAC 5-4-6(d)(3). A map showing the facility catch basins and storm drains has been included as Figure 4. A map showing the impervious area of the facility has been included as Figure 5.

Figure 4: Catch Basins and Storm Drains

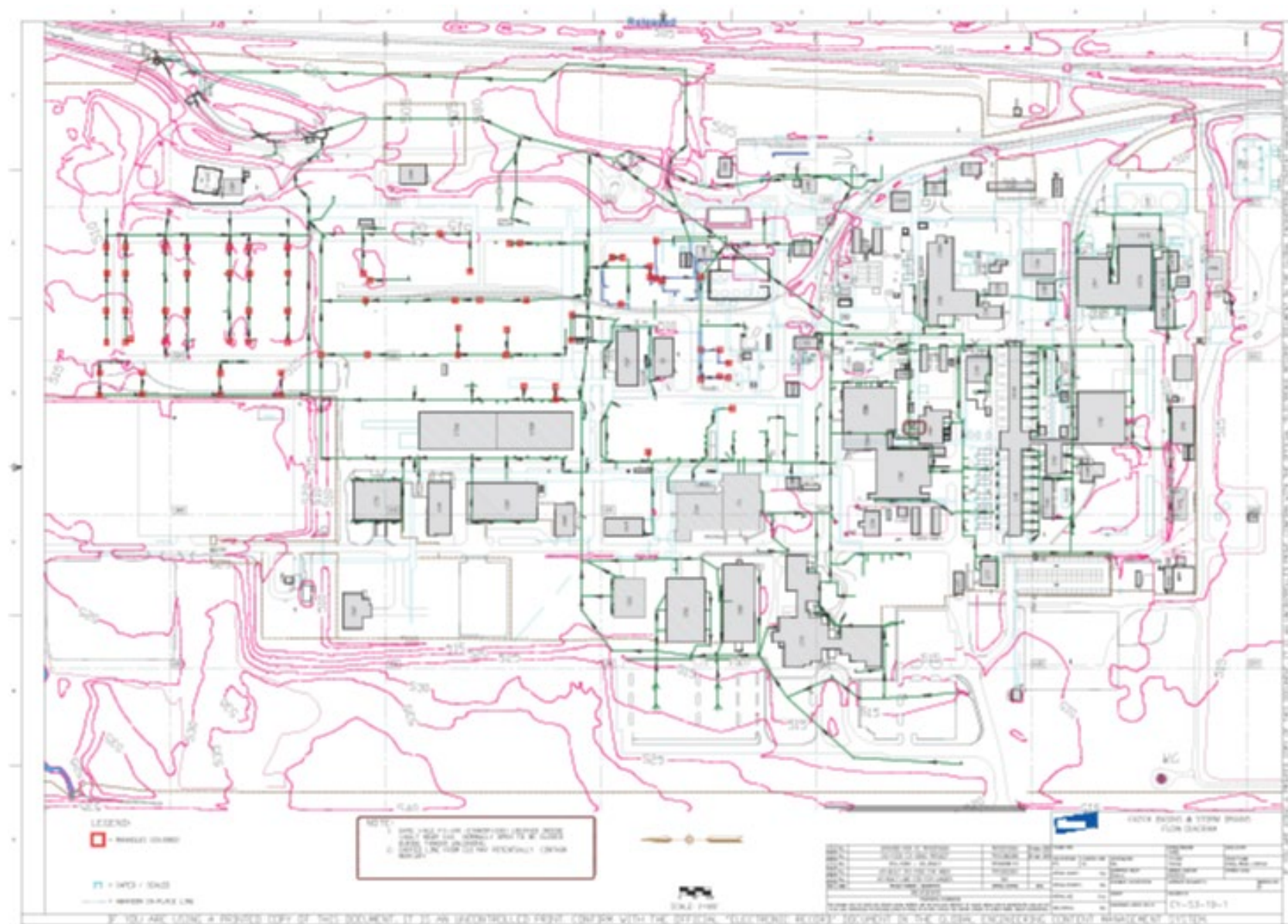
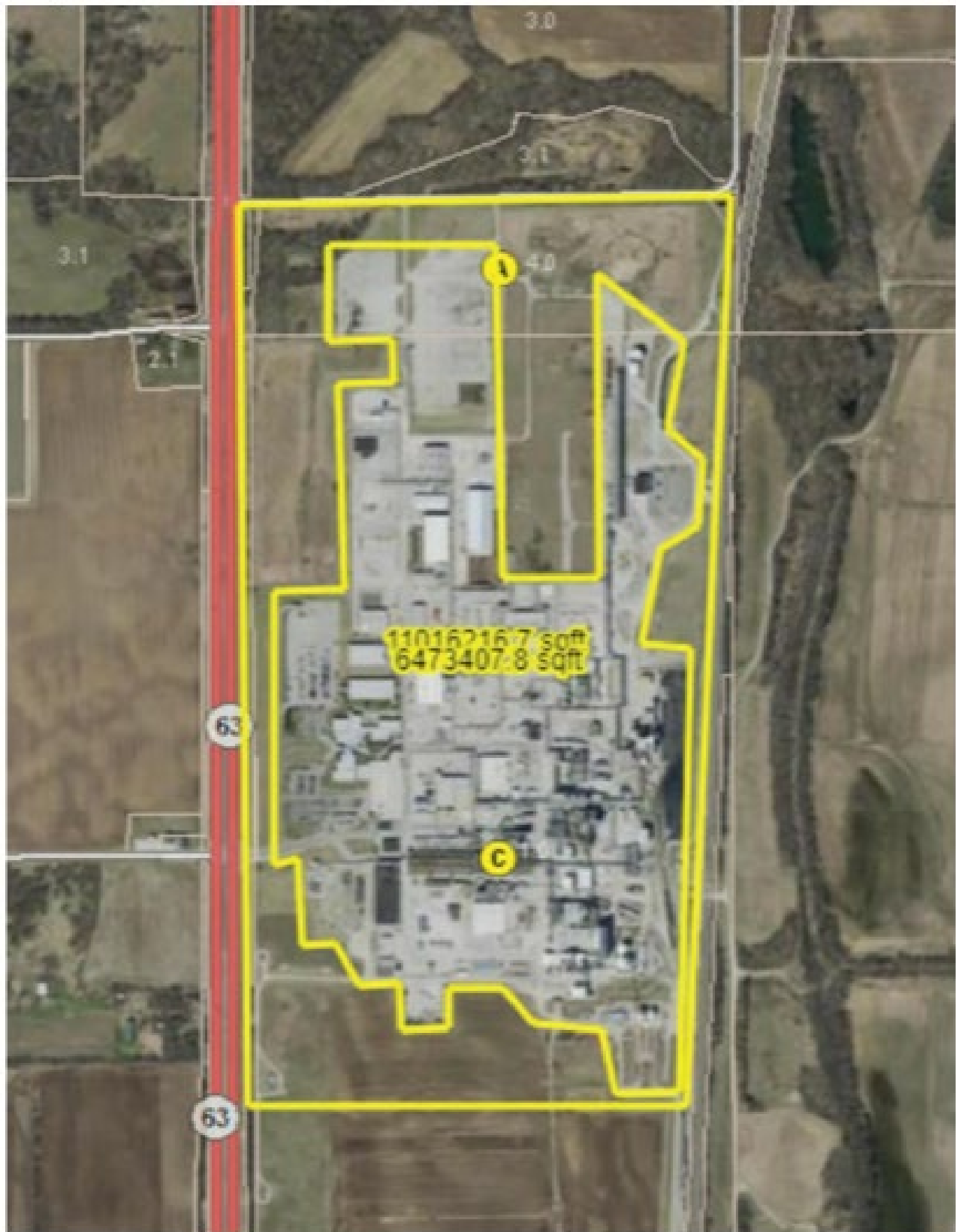


Figure 5: Impervious Area



5.8 Water Treatment Additives

In the event that changes are to be made in the use of water treatment additives that could significantly change the nature of, or increase the discharge concentration of any of the additives contributing to an outfall governed under the permit, the permittee must apply for and obtain approval from IDEM prior to such discharge. Discharges of any such additives must meet Indiana water quality standards. The permittee must apply for permission to use water treatment additives by completing and submitting State Form 50000 (Application for Approval to Use Water Treatment Additives) available at: <https://www.in.gov/ide/forms/ide-agency-forms/> and submitting any needed supplemental information. In the review and approval process, IDEM determines, based on the information submitted with the application, whether the use of any new or changed water treatment additives/chemicals or dosage rates could potentially cause the discharge from any permitted outfall to cause chronic or acute toxicity in the receiving water.

The authority for this requirement can be found under one or more of the following: 327 IAC 5-2-8(11)(B), which generally requires advance notice of any planned changes in the permitted facility, any activity, or other circumstances that the permittee has reason to believe may result in noncompliance with permit requirements; 327 IAC 5-2-8(11)(F)(ii), which generally requires notice as soon as possible of any planned physical alterations or additions to the permitted facility if the alteration or addition could significantly change the nature of, or increase the quantity of, pollutants discharged; and 327 IAC 5-2-9(2) which generally requires notice as soon as the discharger knows or has reason to know that the discharger has begun or expects to begin to use or manufacture, as an intermediate or final product or byproduct, any toxic pollutant that was not reported in the permit application.

The following is a list of water treatment additives currently approved for use at the facility:

<u>Supplier</u>	<u>WTA</u>	<u>Outfall</u>	<u>Purpose</u>
Nalco	BC1011	001	Boiler feedwater oxygen scavenger
Nalco	22310	001	Boiler feedwater scale inhibitor
Nalco	8735	001	Boiler feedwater RO system pH stabilizer
Nalco	CL-50	001	Potable water system deposit and corrosion control
Nalco	3DT231	001	Cooling towers corrosion and deposit inhibitor
Nalco	7408 (sodium bisulfite)	001	Boiler feedwater oxygen scavenger, chlorine scavenger
Nalco	Permatreat PC-191T	001	Boiler feedwater RO system antiscalant
HACH	BioTector B7000 Reagent	001	total organic carbon analyzers
HACH	BioTector Base Reagent	001	total organic carbon analyzers
Thermo Scientific	TRO Analyzer Reagent	001	total residual chlorine detector
Nalco	1820	001	Boiler feedwater corrosion inhibitor
Various	Chlorine	001	Noncontact cooling water treatment
Brenntag	Sodium hypochlorite	001	Potable water and cooling tower treatment
Various	Sulfuric acid	001	Cooling tower treatment
Various	Phosphoric acid	001	Nutrient additions in MBR for pH control
Brenntag	Sodium hydroxide	001	MBR pH control
Suez	Foamtrol AF3031	001	MBR anti-foam

6.0 PERMIT DRAFT DISCUSSION

6.1 Discharge Limitations, Monitoring Conditions and Rationale

The proposed final effluent limitations are based on the more stringent of the Indiana water quality-based effluent limitations (WQBELs), technology-based effluent limitations (TBELs), or approved total maximum daily loads (TMDLs) and NPDES regulations as appropriate for each regulated outfall. Section 5.3 of this document explains the rationale for the effluent limitations at each Outfall.

Analytical and sampling methods used shall conform to the version of 40 CFR 136 as referenced in 327 IAC 5-2-13(d)(1) and 327 IAC 5-2-1.5. Any modified monitoring conditions have been explained in section 5.3 above.

Outfall 001:

Parameter	Monthly Average	Daily Maximum	Units	Minimum Frequency	Sample Type
Flow	Report	Report	MGD	1 X Daily	24 Hr. Total
Temperature	----	Report	°F	1 X Weekly	Grab
Oil and Grease	Report	Report	mg/l	1 X Weekly	Grab
TRC	0.28	0.55	mg/l	1 X Weekly	Grab
BOD ₅	Report	Report	lbs/day	1 X Weekly	24 Hr. Comp.
TSS	Report	Report	lbs/day	1 X Weekly	24 Hr. Comp.
COD	Report	Report	lbs/day	1 X Weekly	24 Hr. Comp.
Ammonia (as N)	Report	Report	lbs/day	1 X Weekly	24 Hr. Comp.
Phosphorus	1.0	Report	mg/l	2 X Monthly	24 Hr. Comp.
Total Mercury	Report	Report	ng/l	1 X Annually	Grab
Biomonitoring	8.8 TUa / 53 TUC				

Parameter	Daily Minimum	Daily Maximum	Units	Minimum Frequency	Sample Type
pH	6.0	9.0	Std Units	1 X Daily	Grab

Outfall 101:

Parameter	Monthly Average	Daily Maximum	Units	Monthly Average	Daily Maximum	Units	Minimum Frequency	Sample Type
Flow	Report	Report	MGD	----	----	----	1 X Daily	24 Hr. Total
E.coli	----	----	----	125	235	count/100ml	1 X Weekly	Grab
Ammonia (as N)	49	140	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
BOD ₅ Influent	Report	Report	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
BOD ₅ Effluent	66	159	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
COD Influent	Report	Report	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
COD Effluent	273	535	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
TSS	113	321	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
Acetone	0.3	0.8	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
Amyl alcohol	6.8	16.7	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
Chloroform	0.02	0.03	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
Ethanol	6.8	16.7	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
Isopropanol	2.7	6.5	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
Methanol	6.8	15.7	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
Methylene chloride	0.5	1.5	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
Phenol	0.03	0.08	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
Toluene	0.03	0.10	lbs/day	Report	Report	mg/l	2 X Monthly	Composite [*]
Acetonitrile	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
n-Amyl acetate	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
Benzene	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
n-Butyl acetate	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
Chlorobenzene	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
o-Dichlorobenzene	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
1,2-Dichloroethane	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
Diethyl amine	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
Dimethyl sulfoxide	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]

Ethyl acetate	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
n-Heptane	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
n-Hexane	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
Isobutyraldehyde	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
Isopropyl acetate	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
Isopropyl ether	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
Methyl Cellosolve	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
Methyl formate	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
4-Methyl- 2-pentanone	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
Tetrahydrofuran	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
Triethyl amine	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]
Xylenes	Report	Report	lbs/day	Report	Report	mg/l	1 X Annually	Composite [*]

[*] A “composite” sample type means a minimum of four (4) grab samples must be collected at equally spaced time intervals for the duration of the discharge within a twenty-four (24) hour period. The grab samples may be analyzed individually, and the arithmetic mean of the concentrations reported as the value for the twenty-four (24) hour period. Or, a twenty-four (24) hour composite sample may be prepared by combining the individual grab samples in the laboratory before analysis.

“Composite” as defined above is unchanged from the previous permit and is consistent with section 8.3.2 of the U.S. EPA Permit Guidance Document: Pharmaceutical Manufacturing Point Source Category (40 CFR 439).

The permittee requested that the composite sample type described above be permitted for all composite samples collected at internal Outfall 101. The permittee stated that the flow at internal Outfall 101 is very consistent throughout the day, ensuring that time-based composites would be fully representative of daily output. Therefore, IDEM has approved this request.

6.2 Schedule of Compliance

The draft permit contains new water quality-based effluent limits; a monthly average effluent limit for total phosphorus and more stringent monthly average effluent limits for TRC. In accordance with 327 IAC 5-2-12 (see also 40 CFR 122.47(a)), a schedule of compliance is allowed in an NPDES permit when requested and justified by the permittee, but only when appropriate and when the schedule of compliance requires achievement of compliance “as soon as possible” and meets other specified conditions. Before a schedule of compliance can be included in a permit, the permittee must submit a request for the schedule to IDEM and demonstrate that they meet the requirements for such a schedule pursuant to 327 IAC 5-2-12.

6.3 Special Conditions and Other Permit Requirements

There are no special conditions on this permit.

6.4 Spill Response and Reporting Requirement

Reporting requirements associated with the Spill Reporting, Containment, and Response requirements of 327 IAC 2-6.1 are included in Part II.B.2.(d), Part II.B.3.(c), and Part II.C.3. of the NPDES permit. Spills from the permitted facility meeting the definition of a spill under 327 IAC 2-6.1-4(15), the applicability requirements of 327 IAC 2-6.1-1, and the Reportable Spills requirements of 327 IAC 2-6.1-5 (other than those meeting an exclusion under 327 IAC 2-6.1-3 or the criteria outlined below) are subject to the Reporting Responsibilities of 327 IAC 2-6.1-7.

It should be noted that the reporting requirements of 327 IAC 2-6.1 do not apply to those discharges or exceedances that are under the jurisdiction of an applicable permit when the substance in question is covered by the permit and death or acute injury or illness to animals or humans does not occur. In order for a discharge or exceedance to be under the jurisdiction of this NPDES permit, the substance in question (a) must have been discharged in the normal course of operation from an outfall listed in this permit, and (b) must have been discharged from an outfall for which the permittee has authorization to discharge that substance.

6.5 Permit Processing/Public Comment

Pursuant to IC 13-15-5-1, IDEM will publish the draft permit document online at <https://www.in.gov/idem/public-notices/>. Additional information on public participation can be found in the "Citizens' Guide to IDEM", available at <https://www.in.gov/idem/resources/citizens-guide-to-idem/>. A 30-day comment period is available to solicit input from interested parties, including the public.

Appendix A
Technology-Based Effluent Limitation Calculations

Elanco Clinton Laboratories 2022 Permit Renewal - TBEL Calculations
Pharmaceutical Guideline: 40 CFR 439.13 (BAT)

Pharmaceutical Flow	0.2	MGD	Long term average flow per Outfall 101 Form C
Total Flow	3.43	MGD	Highest monthly average 1/2019-1/2022

BOD ₅	221	lbs/day
90% of BOD=	198.9	lbs/day
reduced by 90% =	22.10	lbs/day

COD	478	lbs/day
74% of COD=	353.72	lbs/day
reduced by 74% =	124.28	lbs/day

Technology Based Effluent Limitations						
	Monthly			Monthly		
	Daily Max	Avg		Daily Max	Avg	
BOD ₅	159	66	lbs/day	96	40	mg/l
TSS	321	113	lbs/day	192	68	mg/l
COD	535	273	lbs/day	321	164	mg/l
Cyanide (T) internal*	N/A	N/A	lbs/day	33.5	9.4	mg/l
Ammonia	140.4	49.1	lbs/day	84.1	29.4	mg/l
Acetone	0.8	0.3	lbs/day	0.5	0.2	mg/l
4-methyl-2-pentanone	0.8	0.3	lbs/day	0.5	0.2	mg/l
Isobutyraldehyde	2.0	0.8	lbs/day	1.2	0.5	mg/l
n-Amyl acetate	2.2	0.8	lbs/day	1.3	0.5	mg/l
n-Butyl acetate	2.2	0.8	lbs/day	1.3	0.5	mg/l
Ethyl acetate	2.2	0.8	lbs/day	1.3	0.5	mg/l
Isopropyl acetate	2.2	0.8	lbs/day	1.3	0.5	mg/l
Methyl formate	2.2	0.8	lbs/day	1.3	0.5	mg/l
Amyl alcohol	16.7	6.8	lbs/day	10.0	4.1	mg/l
Ethanol	16.7	6.8	lbs/day	10.0	4.1	mg/l
Isopropanol	6.5	2.7	lbs/day	3.9	1.6	mg/l
Methanol	16.7	6.8	lbs/day	10.0	4.1	mg/l
Methyl Cellosolve	166.9	67.8	lbs/day	100.0	40.6	mg/l
Dimethyl sulfoxide	152.7	62.6	lbs/day	91.5	37.5	mg/l
Triethyl amine	417.3	170.2	lbs/day	250.0	102.0	mg/l
Phenol	0.08	0.03	lbs/day	0.05	0.02	mg/l

Benzene	0.08	0.03	lbs/day	0.05	0.02	mg/l
Toluene	0.10	0.03	lbs/day	0.06	0.02	mg/l
Xylenes	0.05	0.02	lbs/day	0.03	0.01	mg/l
n-Hexane	0.05	0.03	lbs/day	0.03	0.02	mg/l
n-Heptane	0.08	0.03	lbs/day	0.05	0.02	mg/l
Methylene chloride	1.5	0.5	lbs/day	0.9	0.3	mg/l
Chloroform	0.03	0.02	lbs/day	0.02	0.013	mg/l
1,2-dichloroethane	0.7	0.2	lbs/day	0.4	0.1	mg/l
Chlorobenzene	0.25	0.10	lbs/day	0.15	0.06	mg/l
o-Dichlororbenzene	0.25	0.10	lbs/day	0.15	0.06	mg/l
Tetrahydrofuran	14.0	4.3	lbs/day	8.4	2.6	mg/l
Isopropyl ether	14.0	4.3	lbs/day	8.4	2.6	mg/l
Diethyl amine	417.3	170.2	lbs/day	250.0	102.0	mg/l
Acetonitrile	41.7	17.0	lbs/day	25.0	10.2	mg/l

*40 CFR 439.12(g) Compliance with the limitation in paragraph (e) or (f) of this section may be achieved by certifying to the permit issuing authority that the facility's manufacturing processes neither use nor generate cyanide.

Appendix B
Waste Load Allocation

DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

INDIANAPOLIS

OFFICE MEMORANDUM

Date: April 8, 2022

To: Permit File

Thru: Richard Hamblin, Chief **RH**
Industrial NPDES Permits Section
John Elliott, Permits Branch **JE**

From: Nikki Gardner
Industrial NPDES Permits Section

Subject: Wasteload Allocation Report for Elanco Clinton Laboratories in Vermillion County (IN0002852, WLA002637)

A reasonable potential analysis for ammonia (as N) and mercury was completed and water quality-based effluent limitations (WQBELs) for total residual chlorine were calculated for the renewal of the NPDES permit for Elanco Clinton Laboratories in Vermillion County. In addition, toxicity reduction evaluation (TRE) triggers for whole effluent toxicity (WET) were calculated. Discharge is to the Wabash River through a submerged high-rate diffuser outfall structure (Outfall 001). The effluent flow used in the analysis is 3.4 MGD.

The Q7,10 of the Wabash River upstream of Outfall 001 is 1090 cfs. The Wabash River is designated for full-body contact recreation and shall be capable of supporting a well-balanced, warm water aquatic community. Site-specific water quality criteria for lead, included in 327 IAC 2-1-8.9(g), Table 8.9-1, apply to the Wabash River from the Elanco Clinton Laboratories outfall to a point two (2) miles downstream. Lead was not evaluated in this analysis.

The discharge is to the Ohio River basin and is therefore regulated by the rules for the non-Great Lakes system. The Wabash River in the vicinity of Outfall 001 (Assessment Unit INB08G7_04) is on the 2020 303(d) list for PCBs in fish tissue. TMDLs for the Wabash River in this Assessment Unit are established for *E. coli*, total phosphorus and nitrate. The EPA, under Section 303(d) of the Clean Water Act, approved the Wabash River Watershed TMDL report on September 22, 2006. The TMDL does not impact the pollutants considered in this wasteload allocation analysis.

The facility discharges through a submerged high-rate diffuser outfall structure and has been granted an alternate acute mixing zone (AMZ) with an associated dilution factor of 29.2. The AMZ review for the existing diffuser is provided in a report dated October 27, 2008. The approved AMZ for the existing diffuser was incorporated into a permit modification issued June 3, 2009. Since 2009, the discharge flow from the facility has remained consistent with the

maximum monthly average flow of 4 mgd considered in the AMZ approval. Therefore, the dilution factor of 29.2 has been retained for the reasonable potential analysis for ammonia (as N), and calculation of WQBELs for total residual chlorine and acute TRE triggers for WET in support of the permit renewal in 2022.

Ammonia (as N) and mercury were identified as pollutants of concern based on a review of pollutants limited in the current permit, data submitted on Form 2C of the permit renewal application, and pollutants regulated by the federal effluent guidelines for this facility. After identifying the pollutants of concern, preliminary effluent limitations were calculated for ammonia (as N) and mercury.

The monthly average and daily maximum projected effluent quality (PEQ) was calculated for ammonia (as N) and mercury using effluent data submitted as part of the current permit requirements. The PEQs for both pollutants were compared to their respective preliminary effluent limitations (PELs) to determine if there was a reasonable potential to exceed a water quality criterion. The results show that a PEQ does not exceed a PEL for ammonia (as N) or mercury, therefore, there is not a reasonable potential to exceed a water quality criterion for ammonia (as N) or mercury.

The calculations of projected effluent quality are included in Table 1. The reasonable potential results are included in Table 2. Water quality-based effluent limitations (WQBELs) for total residual chlorine are included in Table 3 along with WQBELs for ammonia (as N) for comparison to applicable technology-based effluent limitations. In addition, WQBELs for acute and chronic WET are provided in Table 3 for use as TRE triggers in the permit. Documentation of the wasteload allocation analysis is included as an attachment.

Attachment

TABLE 1
Calculation of Projected Effluent Quality
For Elanco Clinton Laboratories in Vermillion County
Outfall 001 to Wabash River
(IN0002852, WLA002637)

Parameter	Monthly Average PEQ					Daily Maximum PEQ				
	Maximum Monthly Average (mg/l)	Number of Monthly Averages	CV	Multiplying Factor	Monthly Average PEQ (mg/l)	Maximum Daily Sample (mg/l)	Number of Daily Samples	CV	Multiplying Factor	Daily Maximum PEQ (mg/l)
Mercury					0.0000044	0.00000341	23	0.6	1.3	0.0000044
Total Ammonia (as N)										
Summer	0.78	36	1.1	1.2	0.94	3.52	162	2.4	0.7	2.5
Winter	0.78	36	1.1	1.2	0.94	3.52	162	2.4	0.7	2.5

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TABLE 2
Results of Reasonable Potential Statistical Procedure
For Elanco Clinton Laboratories in Vermillion County
Outfall 001 to Wabash River
(IN0002852, WLA002637)

Parameter	Monthly Average Comparison			Daily Maximum Comparison			Reasonable Potential to Exceed?
	Monthly Average PEQ (mg/l)	Monthly Average PEL* (mg/l)	PEQ > PEL?	Daily Maximum PEQ (mg/l)	Daily Maximum PEL* (mg/l)	PEQ > PEL?	
Mercury	0.0000044	0.000012	No	0.0000044	0.00002	No	No
Total Ammonia (as N)							
Summer	0.94	46.6	No	2.5	93.5	No	No
Winter	0.94	46.6	No	2.5	93.5	No	No

* Based on an effluent flow of 3.4 mgd.

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TABLE 3
Water Quality-based Effluent Limitations
For Elanco Clinton Laboratories in Vermillion County
Outfall 001 to Wabash River
(IN0002852, WLA002637)

Parameter	Quality or Concentration*			Quantity or Loading*			Monthly Sampling Frequency
	Monthly Average	Daily Maximum	Units	Monthly Average	Daily Maximum	Units	
Total Ammonia (as N)							
Summer	46.6	93.5	mg/l	1,300	2,700	lbs/day	4
Winter	46.6	93.5	mg/l	1,300	2,700	lbs/day	4
Chlorine (total residual)	0.28	0.55	mg/l	7.9	16	lbs/day	4
Whole Effluent Toxicity							
Acute (with MZ)		8.8	TUa				
Chronic	53		TUc				

* Based on an effluent flow of 3.4 mgd.

4/8/2022

Documentation of Wasteload Allocation Analysis For Discharges in the Non-Great Lakes System

Analysis By: Nikki Gardner

Date: April 8, 2022

Reviewed By: John Elliott

WLA Number: WLA002637

Facility Information

- **Name:** Elanco Clinton Laboratories (formerly Eli Lilly Clinton Laboratories)
- **NPDES Permit Number:** IN0002852
- **Permit Expiration Date:** July 31, 2022
- **County:** Vermillion
- **Purpose of Analysis:** Reasonable potential analysis and reanalyze WQBELs for permit renewal.
- **Outfall Number:** 001 (see Attachment 1)
- **Facility Operations:** Treated pharmaceutical process wastewater, sanitary wastewater, noncontact cooling water, cooling tower blowdown, boiler blowdown, RO reject water, and stormwater.
- **Applicable Effluent Guidelines:** 40 CFR 439 Subpart A; ammonia (as N) is a pollutant with applicable technology-based effluent limitations (TBELs) that is being considered in this wasteload allocation analysis
- **Type of Treatment:** Membrane bioreactor and UV light disinfection (both pharmaceutical process and sanitary wastewater.)
- **Current Permitted Flow:** 3.3 mgd (maximum monthly average flow provided in 2017 permit renewal application Form 2C and used to calculate mass limits for mercury; the current chronic WET TRE triggers are from a 2009 permit modification and were based on a flow of 2.5 mgd)
- **Effluent Flow for WLA Analysis:** 3.4 mgd (the highest monthly average flow in the last two years; January 2020 – December 2021 and occurred in March 2020.)
- **Current Effluent Limits:** Only pollutants with effluent limitations are included in the table.

Parameter	Monthly Average		Daily Maximum		Measurement Frequency
	(mg/l)	(lbs/day)	(mg/l)	(lbs/day)	
TRC	0.32	-	0.55	-	1 X Weekly
BOD5	-	634	-	1525	1 X Weekly
TSS	-	1612	-	5767	1 X Weekly
COD	-	2142	-	4191	1 X Weekly
Ammonia	-	74	-	210	1 X Weekly
Total Mercury					
WQBELs	10 ng/l	0.00028	20 ng/l	0.0006	6 X Yearly
SMV*	11 ng/l	-	Report	-	6 X Yearly
Biomonitoring					
Acute	-	-	8.8 TUa	-	1 X Yearly
Chronic	83 TUc	-	-	-	1 X Yearly

*The SMV limit is an annual average.

Pollutants of Concern and Type of WLA Analysis

Pollutants of Concern and Type of WLA Analysis		
Parameter	Type of Analysis	Reason for Inclusion on Pollutants of Concern List
Ammonia (as N)	RPE	Limited in the current permit. Ammonia (as N) is limited in the federal effluent limitation guidelines (ELGs) for this facility.
Mercury	RPE	SMV previously granted. Facility states SMV no longer needed.
Total Residual Chlorine (TRC)	WQBEL	Limited in current permit. Flow has changed since limits were established.
Whole Effluent Toxicity	TRE Triggers	Monitored in current permit. Flow has changed since toxicity reduction evaluation (TRE) triggers were established.

Receiving Stream Information

- **Receiving Stream:** Wabash River
- **Public Water System Intakes Downstream:** There are no known active public water system intakes downstream of the outfall in the State of Indiana.
- **Designated Stream Use:** The Wabash River is designated for full-body contact recreation and shall be capable of supporting a well-balanced, warm water aquatic community.
- **12 Digit HUC:** 51201081607
- **Assessment Unit (2020):** INB08G7_04
- **303(d) List (20120):** The Wabash River in the vicinity of the outfall is on the 2020 303(d) list of impairments due to PCBs in fish tissue.
- **TMDL Status:** A TMDL (Tetra Tech, Inc. (2006) Wabash River Nutrient and Pathogen TMDL Development) was approved by the U.S. EPA, under Section 303(d) of the Clean Water Act, on September 22, 2006. The impairments addressed in the TMDL for the above

assessment unit are *E. coli* and nutrients. The pollutants included in the TMDL are *E. coli*, total phosphorus and nitrate. The TMDL may impact total phosphorus limitations.

- **Q7,10 (Outfall):** 1090 cfs (Considering that Big Raccoon Creek enters Wabash River upstream of the outfall and a USGS gaging station is located on Big Raccoon Creek, the stream design flows were calculated by a ratio of drainage areas using USGS gaging station 03340500 Wabash River at Montezuma (drainage area of 11,118 mi², Q7,10 of 1,050 cfs, Q1,10 of 981 cfs, Q30,10 of 1,580 cfs, and Q50 of 7,100 cfs) and USGS gaging station 03341300 Big Raccoon Creek at Coxville (drainage area of 448 mi², Q7,10 of 34 cfs, Q1,10 of 33 cfs, Q30,10 of 40 cfs, and Q50 of 285 cfs.) The drainage area upstream of the outfall is 11,666 mi². The drainage area of Big Raccoon Creek at its confluence with Wabash River is 520 mi². Therefore, the stream design flows for 11,146 mi² of drainage area were obtained from USGS gaging station 03340500 and the stream design flows for 520 mi² of drainage area were obtained from USGS gaging station 03341300. The information for the gaging stations was obtained from the book Low-Flow Characteristics for Selected Streams in Indiana by Kathleen K. Fowler and John T. Wilson, published in 2015 by the USGS. The drainage area upstream of the outfall was obtained in part from the book Drainage Areas of Indiana Stream by Richard E. Hoggatt, published in 1975 by the USGS in cooperation with the IDNR and in part using a USGS topo map.)
- **Q1,10 (Outfall):** 1020 cfs
- **Q30,10 (Outfall):** 1630 cfs
- **Q50 (Outfall):** 7450 cfs
- **Dilution Factor:** 29.2 (based on an approved alternate acute mixing zone and documented in an October 27, 2008 WLA report for Eli Lilly Clinton Laboratories)
- **Nearby Dischargers:** None that will impact this analysis.

Calculation of Preliminary Effluent Limitations

Water quality data upstream of the outfall were obtained from fixed water quality monitoring station WB-240 Wabash River near Montezuma Boat Ramp for the period January 2017 through December 2021. Data were limited to the last five (5) years. The background concentration of mercury was set equal to zero because it is a bioaccumulative chemical of concern (BCC). Beginning January 1, 2004, the water quality criteria for a BCC are applied directly to the undiluted discharge for all discharges of a BCC. The background concentration of total residual chlorine (TRC) was set equal to zero because stream data are not available and any contribution from upstream dischargers is not expected to result in measureable concentrations in the receiving stream. For ammonia (as N), summer and winter background concentrations were determined.

The background concentration of a given pollutant was determined by calculating the geometric mean of the instream data of the pollutant. The survey data include values reported as less than the limit of quantitation (LOQ). The values below the LOQ were set equal to one-half of the LOQ. The determination of background concentrations is included as Attachment 2.

The 75th percentile downstream temperature and pH are used to determine the ammonia (as N) criteria. The stream pH and temperature were determined using data from fixed station WB-230

Wabash River at Clinton. Using data from January 2017 through December 2021 the summer/winter 75th percentile temperature and pH values are 26/8.6 °C and 8.5/8.5 s.u., respectively. The data are included in Attachments 3 and 4.

The coefficient of variation used to calculate monthly average and daily maximum PELs was set equal to the default value of 0.6. The number of samples per month used to calculate monthly average PELs was set equal to the frequency of reporting required in the current permit for each pollutant of concern. The spreadsheet used to calculate PELs is included in Attachment 5.

Reasonable Potential Analysis

Calculation of Projected Effluent Quality (PEQ)

Effluent data collected from January 2019 through December 2021 for ammonia (as N) and August 2017 through December 2021 for mercury were obtained from the facility. The data for ammonia (as N) are included in Attachment 6 and the data for mercury are included in Attachment 7. While data for the current permit term are typically used for mercury, the facility identified and eliminated a significant source in March 2019. Therefore, data for the period beginning April 2019 were considered to be representative and were used in the reasonable potential analysis.

Comparison of PEQs to PELs

The reasonable potential analysis is included as Attachment 8. The results of the analysis show that the PEQ does not exceed the PEL for ammonia (as N) or mercury. Therefore, the discharge does not have the reasonable potential to exceed a water quality criterion for ammonia (as N) or mercury.

Calculation of Water Quality-based Effluent Limitations

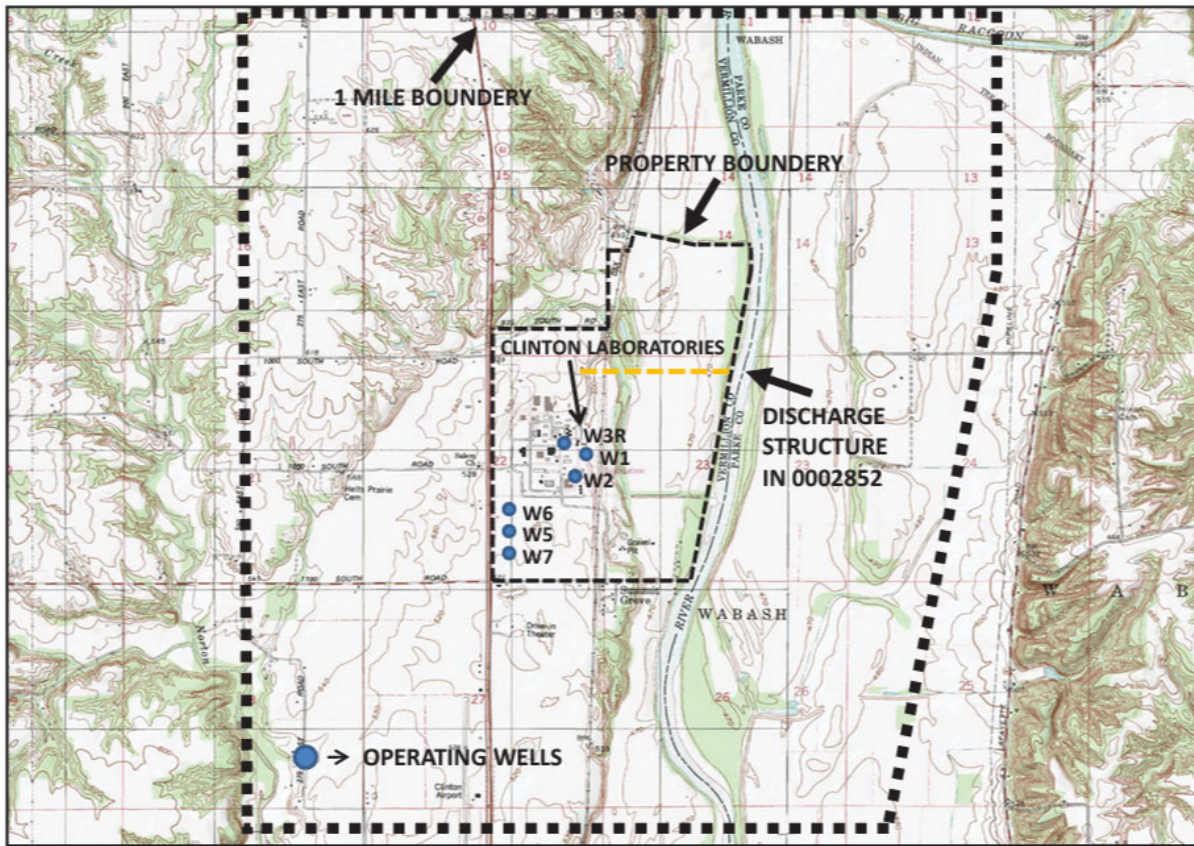
The PELs for TRC in Attachment 5 are based on water quality criteria and may be included in an NPDES permit as water quality-based effluent limitations (WQBELs). In addition, the PELs for acute and chronic WET in Attachment 5 may be included in an NPDES permit as TRE triggers.

List of Attachments

Attachment 1: Topographical Map of Outfall Location
Attachment 2: Calculation of Background Concentrations
Attachment 3: Calculation of Downstream Water Quality Characteristics
Attachment 4: Calculation of Downstream Water Quality Characteristics
Attachment 5: Calculation of Preliminary Effluent Limitations
Attachments 6 and 7: Facility Effluent Data
Attachment 8: Reasonable Potential Analysis

ATTACHMENT I

Fig 1 - TOPOGRAPHIC ONE MILE BOUNDARY MAP OF CLINTON LABORATORIES



ATTACHMENT 2
Calculation of Background Concentrations
Data From Fixed Station WB-240

Date	Summer Ammonia-N (mg/l)	Adjusted Summer Ammonia-N (mg/l)	Date	Winter Ammonia-N (mg/l)	Adjusted Winter Ammonia-N (mg/l)
6/20/2017	< 0.1	0.05	1/5/2017	< 0.1	0.05
7/10/2017	< 0.1	0.05	2/20/2017	< 0.1	0.05
9/26/2017	< 0.1	0.05	3/28/2017	< 0.1	0.05
10/17/2017	< 0.1	0.05	12/28/2017	< 0.1	0.05
11/21/2017	< 0.1	0.05	1/30/2018	< 0.1	0.05
5/22/2018	< 0.1	0.05	2/14/2018	< 0.1	0.05
6/28/2018	< 0.1	0.05	3/21/2018	< 0.1	0.05
7/17/2018	< 0.1	0.05	12/26/2018	< 0.1	0.05
8/22/2018	< 0.1	0.05	3/6/2019	< 0.1	0.05
9/12/2018	< 0.1	0.05	12/11/2019	< 0.1	0.05
10/30/2018	< 0.1	0.05	2/19/2020	< 0.1	0.05
11/20/2018	< 0.1	0.05	3/12/2020	< 0.1	0.05
6/13/2019	< 0.1	0.05	1/12/2021	< 0.1	0.05
7/29/2019	0.1	0.1	3/16/2021	< 0.1	0.05
8/26/2019	< 0.1	0.05	4/13/2021	< 0.1	0.05
9/16/2019	< 0.1	0.05	12/9/2021	< 0.1	0.05
11/13/2019	< 0.1	0.05			
5/27/2020	< 0.1	0.05	Geomean		0.050
6/17/2020	< 0.1	0.05			
7/27/2020	< 0.1	0.05			
8/31/2020	< 0.1	0.05			
9/22/2020	< 0.1	0.05			
10/21/2020	< 0.1	0.05			
11/24/2020	< 0.1	0.05			
5/19/2021	< 0.1	0.05			
7/13/2021	< 0.1	0.05			
8/24/2021	< 0.1	0.05			
9/15/2021	< 0.1	0.05			
11/23/2021	< 0.1	0.05			
Geomean		0.051			

ATTACHMENT 3
Calculation of Water Quality Characteristics
Data From Fixed Station WB-230

Date	Summer pH (s.u.)	Date	Winter pH (s.u.)
8/28/2017	8.29	1/5/2017	8.45
9/26/2017	8.11	2/21/2017	8.45
10/17/2017	8.26	3/28/2017	8.63
5/22/2018	8.24	12/28/2017	8.1
8/22/2018	8.05	1/30/2018	8.36
9/12/2018	8.16	2/14/2018	8.33
10/30/2018	8.3	3/21/2018	8.12
11/20/2018	8.33	12/26/2018	8.57
6/13/2019	8.36	3/6/2019	8.26
7/29/2019	8.89	12/11/2019	7.76
8/26/2019	8.15	3/12/2020	8.21
9/16/2019	8.33	1/13/2021	8.6
10/16/2019	8.2	4/13/2021	8.37
11/13/2019	11.6	12/9/2021	8.3
6/17/2020	8.56		
7/27/2020	8.51	75th %	8.5
8/31/2020	8.59		
9/22/2020	8.61		
10/21/2020	8.26		
11/24/2020	8.44		
8/24/2021	8.23		
9/15/2021	8.39		
10/21/2021	8.39		
11/23/2021	8.26		
75th %	8.5		

ATTACHMENT 4
Calculation of Water Quality Characteristics
Data From Fixed Station WB-230

Summer		Winter	
Date	Temperature (°C)	Date	Temperature (°C)
8/28/2017	23.8	1/5/2017	1.5
9/26/2017	25.6	2/21/2017	10.9
10/17/2017	15.2	3/28/2017	13.7
5/22/2018	23.4	12/28/2017	1.9
8/22/2018	25.4	1/30/2018	2.7
9/12/2018	22	2/14/2018	3.0
10/30/2018	12.6	3/21/2018	5.6
11/20/2018	6.1	12/26/2018	4.9
6/13/2019	20.1	3/6/2019	1.7
7/29/2019	26.5	12/11/2019	3.1
8/26/2019	25.6	3/12/2020	9.6
9/16/2019	26.1	1/13/2021	2
10/16/2019	14.1	4/13/2021	14.6
11/13/2019	3.1	12/9/2021	4.1
6/17/2020	26.4		
7/27/2020	28.9	75th %	8.6
8/31/2020	26.8		
9/22/2020	21.1		
10/21/2020	12.6		
11/24/2020	8		
8/24/2021	30.2		
9/15/2021	25.1		
10/21/2021	15.2		
11/23/2021	6.4		
75th %	26		

ATTACHMENT 5

Calculation of Preliminary Effluent Limitations for Discharges in the Non-Great Lakes System (Excluding Discharges to the Ohio River)

General Information	
Facility Name:	Elanco Clinton Laboratories
County:	Vermillion
NPDES Number:	IN0002852
WLA Number:	002637
WLA Report Date:	4/8/2022
Outfall:	001
Receiving Stream:	Wabash River

Receiving Stream Questions (Yes or No)	
Acute Mixing Zone Allowed?	Yes
Public Water System (PWS) Intake Downstream?	No
Industrial Water Supply (IWS) Intake Downstream?	No
Interstate Wabash River Discharge?	No
Put-and-Take Trout Fishing?	No
Fish Early Life Stages Present?	Yes

Effluent Flow	=	3.4 mgd
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Receiving Stream Design Flows	
Q1,10 (Outfall)	= 1020 cfs
Q7,10 (Outfall)	= 1090 cfs
Q7,10 (Public Water System Intake)	= cfs
Q7,10 (Industrial Water Supply Intake)	= cfs
Q30,10 (Outfall)	= 1630 cfs
Q50 (Outfall)	= 7450 cfs
Q50 (Public Water System Intake)	= cfs

Ambient Downstream Water Quality Characteristics		
Hardness (50th percentile)	=	mg/l
Chloride (50th percentile)	=	mg/l
Sulfate (50th percentile)	=	mg/l
pH (50th percentile)	=	s.u.
Acute Ammonia-N		
Summer pH (75th percentile)	=	8.5 s.u.
Winter pH (75th percentile)	=	8.5 s.u.
Chronic Ammonia-N		
Summer Temperature (75th percentile)	=	26 C
Summer pH (75th percentile)	=	8.5 s.u.
Winter Temperature (75th percentile)	=	8.6 C
Winter pH (75th percentile)	=	8.5 s.u.

Mixing Zone Dilution			
Dilution Factor (for acute mixing zone)	=	29.2	
	Dilution Fraction	Flow	Location
Chronic Aquatic Life (Except Ammonia)	= 50%	Q7,10	Outfall
Chronic Aquatic Life (Ammonia Only)	= 50%	Q30,10	Outfall
Chronic WET	= 25%	Q7,10	Outfall
Human Noncancer Drinking Water	= 100%	Q7,10	PWS Intake
Human Noncancer Nondrinking Water	= 50%	Q7,10	Outfall
Human Cancer Drinking Water	= 100%	Q50	PWS Intake
Human Cancer Nondrinking Water	= 25%	Q50	Outfall
Public Water Supply	= 100%	Q7,10	PWS Intake
Industrial Water Supply	= 100%	Q7,10	IWS Intake

Metals Translators (dissolved to total recoverable)		
	Acute	Chronic
Aluminum	1.000	1.000
Antimony	1.000	1.000
Arsenic	1.000	1.000
Barium	1.000	1.000
Beryllium	1.000	1.000
Cadmium	#NUM!	#NUM!
Chromium III	0.316	0.860
Cobalt	1.000	1.000
Copper	0.960	0.960
Iron	1.000	1.000
Lead	#NUM!	#NUM!
Manganese	1.000	1.000
Molybdenum	1.000	1.000
Nickel	0.998	0.997
Silver	0.85	
Strontium	1.000	1.000
Thallium	1.000	1.000
Tin	1.000	1.000
Titanium	1.000	1.000
Vanadium	1.000	1.000
Zinc	0.978	0.986

Source of Criteria [1]							Background (Outfall) (ug/l)	Background (Intake) (ug/l)	Remove Mixing Zone? (Yes or Blank)	Samples/ Month	CV	Facility Specific CV? (Yes or No)	CAS Number		Indiana Water Quality Criteria for the Non-Great Lakes System (ug/l)							Preliminary Effluent Limitations						
															A	B	C	D	E	F	G							
															A	B	C	D	E	F	G	Aquatic Life Criteria	Human Health Noncancer Criteria		Human Health Cancer Criteria		Add. PWS Criteria	Concentration (ug/l)[3]
Parameters[2]															Acute (AAC)	Chronic (CAC)	Drinking (HNC-D)	Nondrinking (HNC-N)	Drinking (HCC-D)	Nondrinking (HCC-N)	(PWS)	Average	Maximum	Average	Maximum	Type [4]	Basis	
1	1	1	1			8	0		Yes	1	0.6	No	7439976	Mercury[6]	2.4	0.012	0.14	0.15				2	0.012	0.02	0.00034	0.00057	Tier I	CAC[9]
													7664417	Total Ammonia (as N)[7]														
4	4						0.051			4	0.6	No		Summer	3203.00	519.58							46600	93500	1300	2700	Tier I	AAC
4	4						0.05			4	0.6	No		Winter	3203.00	1089.26							46600	93500	1300	2700	Tier I	AAC
1	1						0			4	0.6	No	7782505	Chlorine (total residual)	19	11							280	550	7.9	16	Tier I	AAC
														Whole Effluent Toxicity (WET)														
9							0							Acute (TUa) with Mixing Zone	0.3									8.8				
	9						0							Chronic (TUC)		1.0							53					

[1] Source of Criteria

- 1) Indiana numeric water quality criterion in 327 IAC 2-1-6(a)(3), Table 6-1 or Table 6-2, or in 327 IAC 2-1-6(e).
- 2) "Shall not exceed" (SNE) criterion in 327 IAC 2-1-6(a)(3), Table 6-1 or 327 IAC 2-1-6(a)(6). This criterion is treated as a 4-day average criterion and is implemented in the same manner as the chronic aquatic life criterion.
- 3) Industrial water supply (IWS) criterion in 327 IAC 2-1-6(f). This criterion is treated as a 4-day average criterion and is implemented in the same manner as the chronic aquatic life criterion.
- 4) Acute (1-hour average) and chronic (30-day average) criteria for total ammonia nitrogen in "1999 Update of Ambient Water Quality Criteria for Ammonia," EPA-822-R-99-014, December 1999.
- 5) Tier I criterion derived using the methodology in 327 IAC 2-1-8.2 or 327 IAC 2-1-8.3 when the Method 1 data set is available, or using the methodology in 327 IAC 2-1-8.4, 327 IAC 2-1-8.5 or 327 IAC 2-1-8.6.
- 6) Tier II criterion derived using the methodology in 327 IAC 2-1-8.2 or 327 IAC 2-1-8.3 when the Method 1 data set is not available.
- 7) Site-specific water quality criterion (SSC) in 327 IAC 2-1-8.9, Table 8.9-1 or developed under 327 IAC 2-1-8.9.
- 8) Screening value (SV).

- 9) Numeric interpretation of narrative criterion for toxicity using U.S. EPA recommended water quality criteria for whole effluent toxicity (WET).
- [2] The aquatic life criteria and screening values for all metals except mercury and selenium are in the form of dissolved metal. The aquatic life criteria for mercury and selenium are in the form of total recoverable metal. The human health criteria and screening values and the public water supply screening values for all the metals are in the form of total recoverable metal.
- [3] The preliminary effluent limitations (PELs) for the metals are in the form of total recoverable metal (with the exception of Chromium (VI) which is in the form of dissolved metal).
- [4] See the table "Indiana Water Quality Criteria for the Non-Great Lakes System" for information on the type and source of criteria.
- [5] The above-noted substances are probable or known human carcinogens.
- [6] The above-noted substances are bioaccumulative chemicals of concern (BCCs). Beginning January 1, 2004, the water quality criteria for a BCC shall be applied directly to the undiluted discharge for all discharges of a BCC. To apply the water quality criteria for a BCC directly to the undiluted discharge, enter "Yes" in the "Remove Mixing Zone?" column.
- [7] The above noted substances have a criterion that is a function of an ambient downstream water quality characteristic. See the table "Indiana Water Quality Criteria for the Non-Great Lakes System" for information on the criterion equation.
- [8] Limits based on screening values (as indicated by SV) ARE NOT to be used as water quality-based effluent limitations. These are solely to be used as preliminary effluent limitations.
- [9] The monthly average PEL was set equal to the most stringent WLA because the calculated monthly average PEL exceeded the most stringent WLA and a facility-specific CV was not determined.
- [10] The ambient downstream water quality characteristic must be entered for both chloride and sulfate and it cannot exceed the applicable chronic aquatic life or "shall not exceed" criterion for the substance. Preliminary effluent limitations (PELs) for chloride and sulfate shall not be used to establish water quality-based effluent limitations that do not ensure the water quality criteria for both substances are achieved in the receiving waterbody.

Last revised: July 11, 2013

ATTACHMENT 6
Effluent Data for Elanco Clinton Laboratories

Date	Ammonia (as N) (mg/l)	
	Daily	Monthly Average
1/6/2019	0.05	
1/13/2019	0.05	
1/20/2019	0.05	
1/27/2019	0.05	0.050
2/3/2019	0.05	
2/10/2019	0.06	
2/17/2019	0.05	
2/24/2019	0.05	0.053
3/3/2019	0.05	
3/10/2019	0.12	
3/17/2019	0.07	
3/24/2019	0.05	
3/31/2019	0.05	0.068
4/7/2019	0.05	
4/14/2019	0.07	
4/21/2019	0.05	
4/28/2019	0.05	0.055
5/5/2019	0.09	
5/7/2019	0.08	
5/9/2019	0.06	
5/12/2019	0.2	
5/19/2019	0.05	
5/26/2019	0.14	0.10
6/2/2019	0.05	
6/9/2019	0.05	
6/16/2019	0.06	
6/23/2019	0.05	
6/30/2019	0.11	0.064
7/7/2019	0.05	
7/14/2019	0.05	
7/21/2019	0.05	
7/28/2019	0.05	0.050
8/4/2019	0.07	
8/11/2019	0.05	
8/18/2019	0.22	
8/25/2019	0.07	0.10
9/2/2019	0.05	
9/8/2019	0.05	
9/15/2019	0.05	
9/22/2019	0.05	
9/29/2019	0.05	0.050
10/6/2019	0.05	
10/13/2019	0.05	
10/20/2019	0.05	

Date	Ammonia (as N) (mg/l)	
	Daily	Monthly Average
10/27/2019	0.05	0.050
11/3/2019	0.05	
11/10/2019	0.05	
11/17/2019	0.05	
11/24/2019	0.05	0.050
12/1/2019	0.05	
12/8/2019	0.05	
12/15/2019	0.05	
12/22/2019	0.05	
12/29/2019	0.05	0.050
1/5/2020	0.05	
1/12/2020	0.05	
1/19/2020	0.05	
1/26/2020	0.05	0.050
2/2/2020	0.1	
2/9/2020	0.1	
2/16/2020	0.1	
2/23/2020	0.1	0.10
3/1/2020	0.1	
3/8/2020	0.1	
3/15/2020	0.1	
3/22/2020	0.1	
3/29/2020	0.1	0.10
4/5/2020	0.1	
4/12/2020	0.1	
4/19/2020	0.1	
4/26/2020	0.1	0.10
5/3/2020	0.14	
5/5/2020	0.1	
5/7/2020	0.1	
5/10/2020	0.1	
5/17/2020	0.1	
5/25/2020	0.1	
5/31/2020	0.1	0.11
6/7/2020	0.1	
6/14/2020	0.1	
6/21/2020	0.1	
6/28/2020	0.1	0.10
7/5/2020	0.1	
7/12/2020	0.1	
7/19/2020	0.1	
7/26/2020	0.1	0.10
8/2/2020	3.52	
8/9/2020	0.1	
8/16/2020	0.1	
8/23/2020	0.1	
8/30/2020	0.1	0.78

Date	Ammonia (as N) (mg/l)	
	Daily	Monthly Average
9/7/2020	0.1	
9/13/2020	0.1	
9/21/2020	0.1	
9/27/2020	0.1	0.10
10/4/2020	0.1	
10/11/2020	0.1	
10/18/2020	0.1	
10/25/2020	0.1	0.10
11/1/2020	0.19	
11/8/2020	0.1	
11/15/2020	0.1	
11/22/2020	0.1	
11/29/2020	0.1	0.12
12/6/2020	0.14	
12/13/2020	0.1	
12/20/2020	0.1	
12/27/2020	0.1	0.11
1/3/2021	0.1	
1/10/2021	0.1	
1/17/2021	0.1	
1/24/2021	0.1	
1/31/2021	0.1	0.10
2/7/2021	0.1	
2/14/2021	0.1	
2/21/2021	0.1	
2/28/2021	0.1	0.10
3/7/2021	0.1	
3/14/2021	0.1	
3/21/2021	0.1	
3/28/2021	0.1	0.10
4/4/2021	0.1	
4/11/2021	0.1	
4/18/2021	0.1	
4/25/2021	0.1	0.10
5/2/2021	0.1	
5/4/2021	0.1	
5/6/2021	0.1	
5/9/2021	0.19	
5/16/2021	0.1	
5/23/2021	0.1	
5/31/2021	0.1	0.11
6/6/2021	0.1	
6/13/2021	0.1	
6/20/2021	0.1	
6/27/2021	0.1	0.10
7/5/2021	0.1	
7/11/2021	0.1	

Date	Ammonia (as N) (mg/l)		
	Daily	Monthly Average	
7/18/2021	0.19	0.12	
7/25/2021	0.1		
8/1/2021	0.1		
8/8/2021	0.1		
8/15/2021	0.1		
8/22/2021	0.1	0.10	
8/29/2021	0.1		
9/6/2021	0.1		
9/12/2021	0.1		
9/19/2021	0.1		
9/26/2021	0.1	0.10	
10/3/2021	0.1		
10/10/2021	0.1		
10/17/2021	0.29		
10/24/2021	0.1		
10/31/2021	0.15	0.15	
11/7/2021	0.1		
11/14/2021	0.1		
11/21/2021	0.1		
11/28/2021	0.1		
12/5/2021	0.10	0.10	
12/12/2021	0.10		
12/19/2021	0.10		
12/26/2021	0.10		
Outlier Analysis	mean	0.11	
	std	0.27	
	mean + 3std	0.93	
Reasonable	n	162	36
Potential	CV	2.4	1.1
Analysis	max	3.52	0.78

ATTACHMENT 7
Effluent Data for Elanco Clinton Laboratories

Date	Mercury (ng/l)	
	Daily	Adjusted Daily
8/1/2017	5.63	*
10/3/2017	3.56	*
12/5/2017	6.78	*
2/6/2018	4.53	*
4/3/2018	17.7	*
6/5/2018	15.0	*
8/7/2018	2.19	*
10/3/2018	16.11	*
12/7/2018	8.85	*
2/6/2019	141	*
2/20/2019	36.2	*
2/28/2019	65.93	*
2/28/2019	20.6	*
3/20/2019	90.8	*
3/27/2019	47.38	*
3/27/2019	3.96	*
4/4/2019	2.95	2.95
4/10/2019	3.18	3.18
4/10/2019	3.41	3.41
6/5/2019	2.65	2.65
8/7/2019	3.02	3.02
10/10/2019	1.54	1.54
10/16/2019	1.09	1.09
10/16/2019	0.63	0.63
12/5/2019	0.8	0.8
12/19/2019	0.91	0.91
12/19/2019	1.02	1.02
2/6/2020	0.83	0.83
4/1/2020	2.73	2.73
6/3/2020	2.11	2.11
8/5/2020	1.54	1.54
10/8/2020	1.47	1.47
12/2/2020	0.5	0.5
2/9/2021	0.5	0.5
4/6/2021	0.85	0.85
6/11/2021	1.15	1.15
8/2/2021	1	1
10/6/2021	0.5	0.5
12/8/2021	0.75	0.75
Outlier Analysis	mean	1.5
	std	0.97
	mean + 3std	4.4
Reasonable Potential Analysis	n	23
	CV	0.6
	max	3.41

ATTACHMENT 8

Reasonable Potential Statistical Procedure for Discharges in the Non-Great Lakes System (Excluding Discharges to the Ohio River)

Facility Name: Elanco Clinton Laboratories NPDES Number: IN0002852 WLA Number: 002637 WLA Report Date: 4/8/2022 Outfall: 001 Receiving Stream: Wabash River		Monthly Average Determination							Daily Maximum Determination						
Parameters	Reasonable Potential to Exceed? (Yes or No)*	Maximum Monthly Average (ug/l)	Number of Monthly Averages	CV	MF	PEQ (ug/l)	PEL (ug/l)	PEQ > PEL?	Maximum Daily Sample (ug/l)	Number of Daily Samples	CV	MF	PEQ (ug/l)	PEL (ug/l)	PEQ > PEL?
Mercury	No					0.0044	0.012	No	0.00341	23	0.6	1.3	0.0044	0.02	No
Total Ammonia (as N)															
Summer	No	780	36	1.1	1.2	940	46600	No	3520	162	2.4	0.7	2500	93500	No
Winter	No	780	36	1.1	1.2	940	46600	No	3520	162	2.4	0.7	2500	93500	No

* Reasonable Potential to Exceed:

- 1) "Yes I" means that a projected effluent quality (PEQ) exceeded a preliminary effluent limitation (PEL) based on a Tier I criterion.
- 2) "Yes II" means that a PEQ exceeded a PEL based on a Tier II criterion.
- 3) "Yes SSC" means that a PEQ exceeded a PEL based on a site-specific criterion.
- 4) "No" means that a PEQ did not exceed a PEL.
- 5) "Evaluate Criteria" means that a PEQ exceeded a PEL based on a screening value.